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DEPARTAMENTO DE ESTOMATOLOGÍA I

TESIS DOCTORAL

Estudio del impacto en la calidad de vida del paciente subsidiario de tratamiento prostodóntico mediante el desarrollo y la aplicación de índices específicos

MEMORIA PARA OPTAR AL GRADO DE DOCTORA

PRESENTADA POR

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CERTIFICA

Que el trabajo de investigación titulado: “Estudio del impacto en la calidad de vida del paciente subsidiario de tratamiento prostodóntico mediante el desarrollo y la aplicación de índices específicos”, del que es autora Carmen Perea Urbano, ha sido realizado bajo mi dirección y supervisión, y reúne en su introducción, objetivos, antecedentes y justificación, artículos, discusión, conclusión y resúmenes, los requisitos requeridos para su presentación y defensa.

Y para que conste y surta los efectos oportunos, firmo este certificado en Madrid, a 13 de enero de 2016.

Fdo. Profa. Dra. Raquel Castillo de Oyagüe

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DEDICATORIA

Dedico esta Tesis a mi madre, mi padre y mi hermana, por confiar en mí y ser mi apoyo incondicional. Esta Tesis es también vuestra.

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1. RESUMEN

1. RESUMEN

Título: "Estudio del impacto en la calidad de vida del paciente subsidiario de tratamiento prostodóntico mediante el desarrollo y la aplicación de índices específicos".

Resumen:

El enfoque actual del concepto de salud, que incluye entre sus metas el apropiado funcionamiento y bienestar de los pacientes, conduce a los clínicos a medir la efectividad del tratamiento y a evaluar el impacto de la terapia en el receptor. En nuestro campo, es esencial que los odontólogos comprendamos el concepto de "Calidad de vida asociada a la salud oral" ('Oral health-related quality of life: OHRQoL') y que conozcamos los instrumentos psicométricos diseñados para valorarla.

El manejo de estas medidas de OHRQoL permitirá integrarlas sistemáticamente en ensayos clínicos y programas de salud para evaluar la satisfacción del paciente. Por tanto, los principales objetivos de este trabajo fueron: *1)* comprender y aplicar la base psicométrica y psicofísica de los instrumentos de medida de OHRQoL, 2) validar un cuestionario específico para portadores de prótesis sobre implantes cementadas, y finalmente, *3)* desarrollar un nuevo cuestionario, corto y específico para evaluar la "Calidad de vida asociada a la estética oral" ('Oral aesthetic-related quality of life: OARQoL'). 'OARQoL' es un concepto original de esta investigación propuesto para incluir los parámetros estéticos en pacientes edéntulos.

La presente Tesis Doctoral está estructurada en tres artículos de impacto correlativos publicados en *Medicina Oral, Patología Oral y Cirugía Bucal,* revista J.C.R situada en el tercer cuartil de la especialidad: 'Dentistry, Oral Surgery &

Medicine' (posición: 52/82 e índice de impacto: 1.095 en 2013, año en el que se publicó el primer artículo); y en *Journal of Dentistry*, revista J.C.R. situada en el primer cuartil de la misma especialidad (posición: 13/87 e índice de impacto: 2.749 en 2015, año en el que fueron publicados los artículos segundo y tercero).

En el primer artículo: ***'Oral health-related quality of life in complete denture wearers depending on their socio-demographic background, prosthetic-related factors and clinical condition',*** se investigó el impacto en la OHRQoL del tratamiento mediante prótesis completa. Para ello se administró el cuestionario genérico "Perfil de impacto de salud oral validado en España" ('Oral health impact profile: OHIP.14sp') a 51 pacientes portadores de prótesis completa recabándose también los posibles factores moduladores: datos socio-demográficos, de salud oral y relacionados con la prótesis. Los dominios con mayor impacto en la salud bucal fueron: "Limitación funcional" y "Dolor físico". Se concluyó que los factores que modulan la autopercepción del bienestar fueron la *Localización de la prótesis* (siendo la prótesis inferior menos confortable), así como ser portador de prótesis completa *Bimaxilar* y por último no padecer *Candidiasis* y precisar un *Cambio o reparación de la prótesis*.

En el segundo artículo: '***Validation of the ´Quality of life with implant prostheses (QoLIP-10)' questionnaire for wearers of cement- retained implant-supported restorations',*** se validó el cuestionario específico "Calidad de vida con implantoprótesis" ('Quality of life with implant-prostheses: QoLIP-10') para evaluar el impacto de las rehabilitaciones cementadas en la OHRQoL. Ochenta y cuatro pacientes con implantoprótesis parciales se clasificaron en cuatro grupos: cementadas y atornilladas, cada una de ellas sobre 2 implantes y sobre 3-5 fijaciones. Todos los participantes cumplimentaron el QoLIP-10 y el OHIP-14sp. Se recogieron asimismo datos relativos a la satisfacción global, socio-demográficos, de salud y relacionados con

la prótesis. El QoLIP-10 confirmó su capacidad psicométrica para pacientes portadores de implantoprótesis cementadas (las atornilladas se testaron como grupo control). Concluimos que la extensión y el tipo de retención de la prótesis afecta a la calidad de vida, de modo que la peor calidad de vida correspondía a pacientes con prótesis cementadas en brechas largas, mientras que las prótesis cementadas cortas mejoraban significativamente la percepción de OHRQoL.

Finalmente en el tercer artículo: ***'Oral aesthetic-related quality of life of muco-supported prosthesis and implant-retained overdenture wearers assessed by a new, short, specific scale (QoLDAS-9)',*** se diseñó y validó el primer cuestionario para evaluar la "Calidad de vida asociada a la estética oral" ('Oral aesthetic-related quality of life: OARQoL') de los pacientes rehabilitados protéticamente. Dicha medida específica se denominó "Calidad de vida asociada con la satisfacción estética dental" ('Quality of life with dental aesthetic-satisfaction: QoLDAS'). Setenta sujetos portadores de prótesis completas y sobredentaduras respondieron las preguntas del QoLDAS-9 y del OHIP-20sp. El QoLDAS demostró ser fiable y válido para evaluar la OARQoL de estos pacientes. El análisis factorial confirmó la existencia de tres dimensiones ("Estética psico-facial", "Estética interactiva" y "Estética socio-dental"). Los niveles de OARQoL fueron elevados y equiparables para ambos grupos.

Conclusiones generales de la investigación:

Independientemente de haber utilizado cuestionarios genéricos para investigar la OHRQoL en la población de estudio, se validó el índice específico QoLIP-10 para portadores de restauraciones sobre implantes cementadas (siendo éste el único grupo implantoprotético en el que no se había validado con anterioridad).

Una vez el equipo adquirió la experiencia necesaria, el principal objetivo de la investigación pudo llevarse a cabo: diseñar una escala para medir un nuevo y original concepto de OHRQoL, llamado: “Calidad de vida asociada a la estética oral” (‘Oral aesthetic-related quality of life: OARQoL’). Este instrumento (QoLDAS-9), junto con otros índices generales y específicos, permite evaluar completamente los tres factores que describen el éxito clínico en las rehabilitaciones protéticas de pacientes edéntulos: función, confort y *estética*. Esto puede ser decisivo, dado que, hasta la fecha, las escalas genéricas disponibles sólo discriminaban la auto-satisfacción del paciente en términos de función y confort. Por lo tanto, este es el primer índice que se centra en la estética.

El examen clínico realizado en todos los casos permite obtener otras conclusiones. En primer lugar, el uso de prótesis completas convencionales conlleva impactos negativos en la OHRQoL de pacientes desdentados, principalmente en cuanto a las prótesis inferiores que requieren reparación o sustitución, con una prótesis completa como antagonista. Además, el índice QoLIP-10, mostró que la satisfacción del paciente depende del tipo y extensión de la restauración sobre implantes. El bienestar del paciente también fue modulado por la variable de estudio *Quejas con la boca*. Por otra parte, las prótesis completas y las sobredentaduras son opciones de tratamiento predecibles para mejorar la OARQoL, mostrando ambos grupos niveles comparablemente elevados. En términos de satisfacción estética, los grados superiores de educación conducen a una menor OARQoL utilizando el índice QoLDAS-9. Por consiguiente, la información proporcionada en los tres artículos será útil para lograr soluciones más adecuadas orientadas a los sujetos teniendo en cuenta las características particulares de las restauraciones protéticas y también el perfil socio-demográfico y clínico de los futuros pacientes.

2. INTRODUCCIÓN GENERAL

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La definición y la medición de la salud han experimentado una notable evolución durante las últimas décadas como consecuencia de los cambios en los patrones de morbi-mortalidad de la población, así como de avances conceptuales y científicos sobre la salud y sus determinantes.[1] A medida que la ciencia médica ha ido desarrollándose, ha sido necesario ampliar el concepto de salud a la totalidad de la vida del paciente, sin restringirse a las manifestaciones biológicas.[2] Actualmente la salud se define como un recurso que incluye capacidades personales, sociales, físicas y psicológicas, y permite a las personas afrontar su entorno (interpersonal, social, biológico y físico) para concretar sus aspiraciones y satisfacer sus necesidades.[3] Por tanto, la salud no es únicamente la ausencia de enfermedad, sino que engloba nociones de bienestar físico, mental y social.[4] Por ello, el concepto de calidad de vida se ha introducido como un criterio más a considerar cuando se describe el estado de salud de una persona, definiéndose como *"la percepción personal de un individuo de su situación vital, dentro del contexto socio-cultural en que vive, en relación con sus objetivos, expectativas, valores e intereses,*[5] *los cuales están relacionados entre sí, de forma compleja, con la salud física, el estado psicológico, el grado de independencia, las relaciones sociales y las creencias religiosas"*.[6]

Extrapolando este conocimiento al campo de la odontología encontramos que la Organización Mundial de la Salud (O.M.S) define la "Calidad de vida asociada a la salud oral" ('Oral health-related quality of life, en adelante, OHRQoL') como: "*la percepción que tiene el individuo del grado de disfrute con respecto a su dentición, así como en lo referente a los tejidos duros y blandos de la cavidad bucal en el desempeño de las actividades diarias, teniendo en cuenta sus circunstancias presentes y pasadas,*

sus implicaciones en el cuidado, expectativas y paradigmas acorde al sistema de valores, dentro del contexto socio-cultural".[7]

Estas modernas definiciones de salud y de calidad de vida relacionada con la salud oral han promovido el desarrollo de índices que permiten captar la salud en sus múltiples dimensiones.[8] Dichas escalas de medición incorporan la perspectiva de las propias personas y consiguen información sobre su estado funcional y su bienestar, expresando una correlación positiva con parámetros fisiopatológicos.[9]

El método aceptado para determinar y evaluar de una forma válida el impacto en la vida diaria del individuo y en la sensación de bienestar es la administración de cuestionarios.[8] Estos instrumentos han cobrado un gran impulso en la última década como resultado de la creciente preocupación sobre el impacto de las condiciones orales en la calidad de vida de las personas.[10]

Stewart y cols.[11] describieron en 1988 los siguientes requerimientos conceptuales, estadísticos y pragmáticos para los cuestionarios de salud oral: *1)* deben representar múltiples conceptos y estados de salud relacionados con el funcionamiento general y el bienestar; *2)* deben tener buenas propiedades psicométricas (fiabilidad y validez)[11] y *3)* deben ser simples y fáciles de utilizar para los procedimientos clínicos.[11,12]

Existen diferentes criterios a la hora de clasificar los instrumentos de medida de la OHRQoL, aunque el más reconocido es el propuesto por Guyatt y cols.,[13] que distingue entre instrumentos genéricos y específicos. Los instrumentos genéricos no hacen referencia, ni están relacionados con ningún tipo de enfermedad concreta. Se pueden aplicar tanto a la población general como a grupos delimitados de pacientes, dado que suelen incluir un amplio espectro de dimensiones de la OHRQoL. Sin embargo, los índices específicos se centran en aspectos concretos del estado de salud.

La base para este tipo de aproximación es el incremento potencial de la capacidad del instrumento para detectar mejoras o deterioros de la OHRQoL a lo largo del tiempo (sensibilidad al cambio) al incluir cuestiones relacionadas con el problema definido.

Por otra parte, la individualidad del ser humano y su influencia en la auto-percepción de salud oral hacen necesario comparar la OHRQoL entre países.[10] El uso de las medidas de salud en diferentes entornos lingüísticos y socio-culturales plantea preguntas sobre los valores reflejados en estas escalas.[14] Por tanto, cuando aplicamos un cuestionario en poblaciones e idiomas distintos a los originales es imperativo revisar sus propiedades psicométricas. La traducción de estas herramientas a otras lenguas y su validación son pasos importantes para evaluar la influencia social y cultural en la percepción de OHRQoL.[10,14]

En los últimos años, estas herramientas o cuestionarios de calidad de vida se emplean crecientemente en investigación y en la práctica clínica como medida de resultados de intervenciones terapéuticas o para establecer comparaciones entre diversas poblaciones o entre grupos con diferentes patologías.[15] En definitiva, un mejor conocimiento de los sistemas de evaluación para medir la calidad de vida permitirá incorporar estos instrumentos de forma satisfactoria en la evaluación integral de los individuos, en la conducción de ensayos y en la investigación.[16]

3. REVISIÓN DE LA LITERATURA

3. REVISIÓN DE LA LITERATURA

En la actualidad estamos asistiendo al desarrollo de múltiples herramientas e instrumentos dirigidos a evaluar cómo se modifica la OHRQoL de los pacientes sometidos a diferentes tratamientos (en el caso del presente proyecto, protéticos) y cuál es su grado de satisfacción respecto a las restauraciones que reciben.[17]

Los instrumentos específicos muestran un mayor poder de discriminación.[13,18] Cuando se pretende dar respuesta a problemas concretos de salud, se buscan escalas que sean sensibles a variaciones de OHRQoL en ámbitos determinados.[19] Sin embargo, cuando tratamos de comprobar el impacto que una intervención desencadena en el estado de salud, hay que recordar que ésta también se ve condicionada por las características inherentes del propio paciente.[13] Por ello, como norma básica, suele ser aconsejable incluir en el estudio tanto instrumentos específicos como genéricos.[19]

Tradicionalmente, el éxito clínico de un tratamiento protético se ha descrito como una combinación de función, confort y estética.[20-24] Dado que esta triada influye en la aceptación del tratamiento, se recomienda discriminar el impacto de estos aspectos en la OHRQoL de los pacientes.[25]

En esta línea, la presente revisión bibliográfica se ha centrado en tres escenarios distintos. El primero consiste en una aproximación a los cuestionarios genéricos, versando concretamente sobre el OHIP14-sp[12,26,27] que es uno de los índices más comúnmente aplicados para situaciones como el edentulismo. La segunda parte de esta revisión se ocupa del estudio de un instrumento específico recientemente validado en nuestro país para usuarios de implantoprótesis (QoLIP-10).[28,29] Finalmente, en la tercera parte se describen los principios de psicofísica y psicometría requeridos de cara al diseño de nuevas escalas de medida relacionadas con el concepto de OHRQoL.

3.1. Primera parte: cuestionario OHIP (Perfil de Impacto de Salud Oral / Oral Health Impact Profile)

3.1.1. Conceptos básicos

En 1994, Slade y Spencer[26] desarrollaron el "Perfil de impacto de salud oral" ('Oral Health Impact Profile: OHIP'), que es uno de los instrumentos más conocidos para evaluar la calidad de vida relacionada con el estado de salud oral de los pacientes.[30] Este índice se encuadra en el marco conceptual derivado de la clasificación internacional de deterioro de la salud (*impairment*), dificultad (*disability*) y minusvalía (*handicap*) (ICIDH) desarrollado por la O.M.S. en 1980.[31] El modelo ICIDH engloba los siguientes conceptos clave: deterioro de la salud (deficiencia), limitación funcional, dolor, dificultad y minusvalía; proporcionando una base teórica para la exploración empírica de las relaciones entre varias dimensiones de salud general y oral.[31] Se trata de una noción que fue posteriormente introducida en el campo de la odontología por Locker en 1988[2] y que fue utilizada para identificar los dominios conceptuales en la jerarquía del impacto social.[26]

En este modelo, se capturan siete dimensiones: "Limitación funcional", "Dolor físico", "Malestar psicológico", "Dificultad física", "Dificultad psicológica", "Dificultad social" y "En desventaja/ hándicap". Estas dimensiones o dominios están vinculados de forma lineal para producir un esquema general que se mueve desde un nivel de análisis biológico, de comportamiento y de conducta social. El diagrama también ilustra las posibles relaciones entre los componentes del modelo.[2]

Por otro lado, la enfermedad puede desembocar en deterioro de la salud, definido como cualquier pérdida anatómica, anomalía estructural o perturbación en procesos físicos o psicológicos: la pérdida de un diente, por ejemplo.[2,12] A su vez el

deterioro de la salud puede originar posteriormente una limitación funcional, descrita como la existencia de impedimentos para el desarrollo de las funciones que habitualmente se esperan del cuerpo humano, sus órganos o sistemas.[2] Por ejemplo, dificultad al pronunciar algunos sonidos[26] o restricciones en los movimientos de apertura, lateralidad o cierre.[2] Otra consecuencia del deterioro podría ser el dolor o malestar, físico o psicológico.[26] Cualquiera de ellos puede derivar en dificultad psicológica, física o social, descritas por Locker,[2] que al mismo tiempo se manifiestan como una falta de capacidad para realizar actividades de la vida diaria. Un ejemplo puede ser la mala pronunciación que hace que una persona no sea bien entendida durante una conversación.[26] La consecuencia final es la situación de desventaja que experimentan las personas con dificultad y deterioro debido a que no deseen o no puedan cumplir con las expectativas de la sociedad o los grupos sociales a los que pertenecen.[2]

3.1.2. Desarrollo del OHIP

Slade[26] realizó una adaptación del modelo de salud oral de Locker[2] para desarrollar el cuestionario OHIP, que consta de 49 preguntas, a las cuales se llegó entrevistando a un grupo de pacientes que expresaron, haciendo uso de su propio lenguaje, la consecuencia de los desórdenes orales. Estos enunciados se reformularon en forma de pregunta y se recopilaron en los siete dominios descritos anteriormente.[26]

El OHIP-49 ha demostrado una gran validez y fiabilidad. Sin embargo, el gran número de ítems que contiene limita su uso en ensayos clínicos, en la práctica clínica y en investigación.[32,33] Por ello, Slade[12] publicó en 1997 una forma resumida del OHIP conformado, al igual que el anterior, por siete dimensiones (cada una de ellas con dos preguntas) denominadas: “Limitación funcional”, “Dolor físico”, “Malestar

psicológico", "Dificultad física", "Dificultad psicológica", "Dificultad social" y "En desventaja/ hándicap".

Tanto la versión extendida de 49 ítems del OHIP[26], como las versión corta de 14 preguntas[12], están enfocadas para su empleo en adultos mayores[10], sin embargo, Allen y Locker[32] en 2002 realizaron un estudio en el que revelaron que la versión corta del OHIP podría no ser la más adecuada para pacientes portadores de prótesis debido a la exclusión de los ítems relativos a la masticación por el análisis factorial, entre otros aspectos. Por ello, diseñaron otra versión del cuestionario específica para pacientes rehabilitados con prótesis, el OHIP-20[32], que constaba de 20 preguntas y siete dimensiones idénticas a las del OHIP-49[26] y el OHIP-14[12], el cuál demostró tener excelentes propiedades psicométricas.

3.1.3. Cuantificación del OHIP

En las tres formas del OHIP[12,26,32], las respuestas se cuantifican con una escala tipo Likert,[12,26] codificada con valores que van de 0 a 4 y que determinan la frecuencia de cada evento del siguiente modo: 4 = "muchas veces", 3 = "algunas veces", 2 = "ocasionalmente", 1 = "rara vez" y 0 = "nunca". La puntuación de cualquier variante del OHIP puede ser calculada por tres métodos. El primero, llamado "método de suma simple" ('OHIP-SC') que consiste en la suma del número de ítems que cada sujeto ha respondido como "muchas veces" y "algunas veces". Esto reduce las respuestas a una escala dicotómica. El segundo, llamado "método aditivo" ('OHIP-ADD'), consiste en sumar los códigos de respuesta de las todas las preguntas.[34] Este enfoque asume que los aspectos de la vida diaria descritos por los ítems son equivalentes en términos de severidad o importancia.[35] En el tercero, llamado "método estandarizado-ponderado" ('OHIP-WS'), el código de respuesta de cada ítem se multiplica por el ítem ponderado y

se suma para establecer subescalas de puntuación. Dichas puntuaciones son estandarizadas a una media y una desviación estándar de 1 y después sumadas para obtener una puntuación total.[34] El método estandarizado-ponderado refleja diferencias en la severidad o importancia de eventos asociados con condiciones clínicas de varios tipos.[35] Por otra parte, el método OHIP-ADD y el OHIP-WS son virtualmente idénticos con respecto a la sensibilidad y la especificidad.[34] Debido a esta razón, es más frecuente utilizar el método OHIP-ADD, ya que con el método OHIP-WS el cálculo de la puntuación es más complejo, induciendo más al error. Las respuestas a las preguntas pueden ser calculadas en subescalas separadas para cada dimensión del impacto social del OHIP, y/o en su conjunto, considerando todas las preguntas.[34]

El OHIP fue utilizado en nuestra investigación dado que es una de las medidas más difundidas internacionalmente en estudios clínicos de calidad de vida en adultos mayores. Además, este cuestionario está validado en la población española en sus dos versiones cortas (OHIP-14sp[27] y OHIP-20sp[36]).

3.2. Segunda parte: cuestionario QoLIP-10 (Calidad de vida con Implanto-prótesis)

3.2.1. Conceptos básicos

Las prótesis sobre implantes tratan de asemejarse a la dentición natural en términos de funcionalidad; sin embargo, difieren sustancialmente en su forma, fabricación y biomecánica, lo que puede afectar al bienestar del paciente.[37,38] Como se ha expuesto anteriormente, los cuestionarios específicos son más sensibles para detectar impactos en OHRQoL.[13] Por tanto, y dado que no existían hasta la fecha medidas específicas para valorar la OHRQoL en pacientes portadores de implantoprótesis, Preciado y cols.[28,29] en 2013 decidieron desarrollar un cuestionario corto, específico y válido para evaluar el impacto del tratamiento protético en el bienestar de los pacientes rehabilitados con implantes.

3.2.2. Desarrollo del QoLIP-10

Para elaborar un banco de ítems preliminar, un grupo de expertos seleccionó los dominios más relevantes en OHRQoL en pacientes portadores de prótesis sobre implantes tras una exhaustiva revisión de la literatura. Siguiendo las recomendaciones aceptadas para la elaboración de un nuevo cuestionario[8], el grupo de investigación se reunió con un grupo de 43 pacientes para explorar las áreas del bienestar que pueden verse afectadas por la presencia de rehabilitaciones implantosoportadas.[28]

Al final de este proceso, el comité de expertos identificó tres dominios relevantes para rehabilitaciones sobre implantes: “Biopsicosocial”, “Estética dento-facial” y “Rendimiento funcional”. Del mismo modo, tras la eliminación de preguntas redundantes, se eligieron 10 ítems para conformar el nuevo cuestionario, que se

denominó “Calidad de Vida con Implantoprótesis” (‘Quality of Life with Implant-Prostheses: QoLIP-10’).[28]

El dominio “Biopsicosocial” incluía los siguientes ítems (Q): Q1: dolor, Q2: dificultad a la masticación, Q3: preocupación, Q4: comunicación / relaciones sociales y Q5: actividades diarias. Por su parte, el dominio “Estética dento-facial” quedó integrado por los ítems: Q6: satisfacción con la apariencia de la prótesis, Q7: satisfacción con el realismo de la prótesis y Q8: satisfacción con la sonrisa. Finalmente, el dominio “Rendimiento funcional” estaba configurado por las cuestiones: Q9: dificultad al hablar y Q10: dificultad para llevar a cabo la higiene.[28]

Esta versión original de la escala se aplicó en pacientes portadores de sobredentaduras implantológicas e implantoprótesis híbridas y demostró tener excelentes propiedades psicométricas para evaluar la OHRQoL en estos sujetos.[28]

Sin embargo, existe otra versión adaptada de la escala para pacientes portadores de prótesis sobre implantes atornilladas en la que debido al análisis factorial el ítem 2 (dificultad a la masticación) pasó del dominio “Biopsicosocial” a la dimensión “Rendimiento funcional”. Del mismo modo, el QoLIP-10 demostró tener excelente validez y fiabilidad para determinar la influencia de este tratamiento en el bienestar de los pacientes.[29]

3.2.3. Cuantificación del QoLIP-10

Tanto la versión original[28] como la versión adaptada[29] están diseñadas para ser auto-cumplimentadas en base a una escala tipo Likert[12,26] con códigos proporcionales a los grados de impacto. Los ítems evaluados como < 0 se consideran como impactos negativos, mientras que los valores +1 y +2 representan la parte positiva de cada ítem (ausencia de impacto negativo). Las posibles respuestas son: muy en desacuerdo (-2), en

desacuerdo (-1), indeciso, indiferente o neutro (0), de acuerdo (+1) y muy de acuerdo (+2). La puntuación total es la suma de las puntuaciones (método aditivo: ADD), así que tanto los impactos positivos como los negativos contribuyen a la puntuación final. La puntuación total del QoLIP-10 oscila desde -20 hasta +20, teniendo en cuenta que a mayor puntuación, mayor satisfacción del paciente.[28,29]

Dada la excelente fiabilidad y validez que demostró tener esta escala, fue elegida en el presente trabajo de investigación como medida exploratoria para el estudio de índices específicos y para su validación en el grupo de implantoprótesis en el que aún no había sido testado: las prótesis cementadas sobre implantes.

3.3. Tercera parte: fases para el desarrollo de un instrumento de medición de OHRQoL

La utilización de las escalas de evaluación se basa en la psicofísica y la psicometría. La psicofísica nos aproxima al proceso de cuantificación de la percepción mientras que la psicometría nos permite estudiar la adecuación de la escala al fenómeno objeto de la medición y la calidad de la medida.[39] En esta tercera parte de la revisión se desarrolla el proceso de construcción y validación de un cuestionario de OHRQoL de forma cronológica.

3.3.1. Definición del constructo y propósito de la escala

El modelo conceptual es la razón fundamental para la que se ha creado el cuestionario, con la descripción del aspecto que se quiere medir y la población que se quiere evaluar con dicho instrumento.[39] Ello requiere la realización de una revisión exhaustiva de la bibliografía científica para establecer un marco teórico de referencia y un consenso sobre el contenido y la estructura preliminar que debería tener el instrumento.[40]

3.3.2. Elaboración de los ítems del test y cuantificación de las respuestas

Cuando se opta por diseñar un nuevo test, el primer paso en la escritura de una escala o cuestionario será naturalmente la elaboración de los ítems.[41] Un cuestionario de OHRQoL debe basarse en el paciente como fuente información, reflejando su opinión. Otras fuentes de información pueden ser los hallazgos de la investigación, la revisión bibliográfica y la opinión de los expertos.[42-44]

Para determinar de forma definitiva los ítems y las dimensiones del cuestionario es útil formar grupos de discusión (*focus groups*) con la población diana para conocer lo

que ellos consideran como elementos más importantes del constructo.[45] Sobre el número inicial de ítems que deben redactarse no hay una cantidad óptima establecida, pero se ha constatado que a mayor número inicial de ítems, mayor probabilidad de encontrar en el análisis un conjunto de ítems definitivos con una fiabilidad suficiente.[40]

El siguiente paso en la elaboración de un cuestionario es asignar a cada pregunta un sistema de puntuación que permita cuantificar la variable de estudio *Puntuación del test.* La escala tipo Likert[46] es una escala psicométrica comúnmente utilizada en cuestionarios, en encuestas de investigación y, de acuerdo a la revisión bibliográfica, fue la elegida en este estudio.

Una vez obtenida la puntuación individual de cada ítem, es necesario decidir cómo va a calcularse el resultado total del test. Los diferentes métodos existentes han sido descritos en la primera parte de esta revisión. En esta investigación se optó por el método aditivo (ADD), según el cual se suman todas las puntuaciones asignadas a cada pregunta.[34]

3.2.3. Validez aparente y validez de contenido de un test

Mediante la validación aparente y la validación de contenido se seleccionan los ítems del test que mejor cubran todos los dominios objeto de estudio.[39]

La validez lógica o aparente se refiere al grado en que parece que un cuestionario mide lo que quiere medir a juicio de los propios sujetos.[39]

La validez de contenido es el grado en que la medición abarca la mayor cantidad de dimensiones del concepto que se quiere estudiar; por tanto, se considera que un instrumento es válido por su contenido si contempla todos los aspectos relacionados con el concepto en estudio.[39] Esta faceta de la validez se relaciona con la composición del instrumento y valora si éste contiene una muestra representativa (ítem) de los

componentes del constructo que pretende medir. Supone el examen sistemático del contenido de la herramienta de medición para determinar si sus ítems son relevantes (si todos están relacionados con el concepto que se desea medir) y representativos del dominio que se pretende medir (si representan las características esenciales del constructo y si se encuentran en las proporciones adecuadas). La evaluación de la validez de contenido se basa en juicios de diferente procedencia (revisión de la literatura, opinión de expertos, estudios piloto, etc.). Este proceder debe garantizar, de forma empírica que el contenido del instrumento sea adecuado.[39,47]

La diferencia entre validez aparente y validez de contenido reside en que la evaluación de esta última es un proceso más exhaustivo, y quizás más formal, en el que deberían participar tanto investigadores y profesionales como miembros de la población diana.[47]

3.2.4. Fiabilidad de un test

Una de las principales características que debe cumplir un test es la fiabilidad *(reliability),* que expresa el grado de precisión en la medida de un determinado rasgo psicológico, independientemente del hecho de si es capaz o no de medirlo (validez). La precisión o fiabilidad de un test se puede entender también como el grado en que diferentes subconjuntos de ítems miden un rasgo o comportamiento homogéneo; es decir, el grado en que co-varían, correlacionan o son consistentes entre sí diferentes partes del cuestionario.[48,49] La fiabilidad de un instrumento de medida se valora a través de la consistencia interna, que recoge el grado de coincidencia (homogeneidad) entre los elementos que componen cada escala, es decir, el grado en que los distintos ítems o partes de un cuestionario están relacionados entre sí; o la constancia de los ítems para operar sobre un mismo constructo psicológico de un modo análogo.[48,49] Entre los

diferentes métodos para calcular la fiabilidad, el escogido en el presente trabajo fue el "coeficiente α" (también llamado "*alpha de Cronbach*").[50] el cual se utiliza para ítems continuos.[48,49] Alfa representa la consistencia interna del test: el grado que todos los ítems del test co-varían entre sí. [48,49]

El valor de α depende del grado de co-variación de los ítems: tendrá un valor elevado (cercano a 1) cuando los ítems co-varíen fuertemente entre sí, mientras que asumirá valores cercanos a 0 si los ítems son linealmente independientes (co-variando de forma escasa).[50,51] Sin embargo existen factores que pueden afectar a la fiabilidad del test como son: *1)* las características y tamaño de la muestra: cuanto más homogéneas sean las muestras habrá menos variabilidad y, por tanto, la fiabilidad será menor y a la inversa; y *2)* la longitud del test: cuanto más largo sea un test, mayor será su fiabilidad. Debe interpretarse como un indicador del grado de co-variación entre los ítems y es aconsejable complementarlo con otras técnicas estadísticas como el análisis factorial.[51]

La relación conceptual (homogeneidad de los ítems) se determina mediante la elección de dichos ítems procurando que todos ellos definan el mismo rasgo. Empíricamente, esta homogeneidad se comprueba mediante la "correlación inter-ítem" y la "correlación ítem-total".[44] Lo que revelan directamente estos coeficientes es hasta qué punto las respuestas son lo suficientemente coherentes como para poder concluir que todos los ítems miden el constructo en una misma dirección y, por lo tanto, son sumables en una puntuación total única que representa un rasgo.[52] En este sentido, la regla de oro es que siempre un ítem debe correlacionarse con la puntuación total por encima de 0.20, por lo que los ítems con correlaciones inferiores deben descartarse.[53] En la mayoría de los casos el test más empleado para calcular estas correlaciones es el test de Pearson.[54]

3.2.5. Validez de un test

La validación de un cuestionario es un proceso por el cual se obtiene evidencia para sustentar inferencias.[50] En este apartado, se detallarán los tipos de validez que debe verificar un test.

3.2.5.1. Validez de criterio

La validez de criterio supone un estudio de la relación entre las puntuaciones observadas en el cuestionario y un criterio externo *(gold standard)* que define adecuadamente y de forma independiente aquello que se pretende medir con el instrumento.[39] Una vez establecido el criterio, la validez de la predicción se determina a partir del coeficiente de correlación entre las puntuaciones del cuestionario y los valores del criterio. El tamaño de la correlación se emplea como indicador directo de la validez de criterio del instrumento en cuestión. A mayor correlación, mayor capacidad predictiva del test.[55]

En ocasiones se produce una distinción entre dos tipos de validez de criterio que, aunque no suele ser importante, se emplea con cierta frecuencia. La validez predictiva se refiere a la idoneidad de un instrumento para diferenciar entre el desempeño o las conductas de los individuos respecto a un criterio futuro. La validez concurrente denota la capacidad de un instrumento de distinguir a los individuos que difieren en su condición actual respecto a un criterio. La diferencia entre validez concurrente y predictiva radica, por consiguiente, en que el criterio de referencia se pueda medir concurrentemente con el cuestionario, o que sea preceptivo medirlo *a posteriori*.[56]

3.2.5.2. Validez de constructo

La validez de constructo supone realizar una serie de estudios empíricos que pongan a prueba hipótesis específicas sobre cómo los pacientes que difieren en el constructo de interés, lo hacen a su vez en otras variables relacionadas. Si bien los procedimientos para la validación de constructo son múltiples, a menudo se emplean técnicas de diferenciación de grupos conocidos como el análisis factorial.[57]

La validez convergente y la validez discriminante son dos aspectos de la validez de constructo. La validez convergente se refiere al grado en que se relacionan entre sí distintas formas de medir el mismo constructo. La validez discriminante demuestra que una medida no se correlaciona con otras medidas efectuadas sobre rasgos, dimensiones o constructos diferentes a los que ella mide.[58,59]

3.2.5.2.1. Análisis factorial

El análisis factorial es una técnica de reducción de datos que sirve para encontrar grupos homogéneos de variables a partir de un conjunto numeroso de variables. Estos grupos homogéneos se forman con las variables que se correlacionan mucho entre sí, procurando, inicialmente, que unos grupos sean independientes de otros.[60] Cuando recogemos un gran número de variables de forma simultánea podemos estar interesados en averiguar si las preguntas del cuestionario se agrupan de alguna forma característica. Aplicando un análisis factorial a las respuestas de los sujetos podemos encontrar grupos de variables con significado común y conseguir de este modo reducir el número de dimensiones necesarias para explicar las respuestas de los sujetos.[61]

El análisis factorial puede ser exploratorio o de confirmación. El análisis exploratorio se caracteriza porque no se conoce *a priori* el número de factores, siendo en la aplicación empírica donde se determina dicho número. Por el contrario, en el

análisis de tipo confirmatorio los factores sí que están fijados *a priori*, utilizándose contrastes de hipótesis para su comprobación.[61]

El análisis factorial de un cuestionario o instrumento de medición ayuda a establecer la validez de constructo de lo que estamos midiendo. El análisis factorial es, por tanto, una técnica de reducción de la dimensionalidad de los datos. Su propósito último consiste en buscar el número mínimo de dimensiones capaces de explicar la máxima información contenida en los datos.[60]

El análisis factorial consta de cuatro fases características: el cálculo de una matriz capaz de expresar la variabilidad conjunta de todas las variables, la extracción del número óptimo de factores, la rotación de la solución para facilitar su interpretación y la estimación de los sujetos en las nuevas dimensiones.[44]

I. Paso: cálculo de la matriz:

Para analizar el modelo factorial se puede emplear la medida de adecuación muestral KMO *(Kaiser-Meyer-Olkin)* que contrasta si las correlaciones parciales entre las variables son suficientemente pequeñas.[62,63]

El estadístico KMO varía entre 0 y 1. Puesto que la correlación parcial entre dos variables debe ser pequeña cuando el modelo factorial es adecuado, cuanto más cerca de 1 se sitúe el valor obtenido del KMO, mayor será la relación entre las variables. Los valores menores de 0,5 indican que no debe utilizarse el análisis factorial con los datos muestrales que se están analizando.[62,63]

La prueba de esfericidad de Bartlett contrasta la hipótesis nula de que la matriz de correlaciones es una matriz identidad. Si el nivel crítico es mayor que 0,05 no podremos rechazar la hipótesis nula de esfericidad y, consecuentemente, no podremos asegurar que el modelo factorial sea el adecuado para explicar los datos.[62,63]

II. Paso: extracción de los factores:

Una vez que se ha determinado que el análisis factorial es una técnica apropiada para analizar los datos, debe seleccionarse el método adecuado para la extracción de los factores. El primer objetivo del análisis factorial es determinar cuántas dimensiones está midiendo un test, es decir, cuantas soluciones deben incluirse en la solución factorial. Se han propuesto varios métodos para la extracción de factores y uno de lo más sencillos y utilizados es el "Análisis de componentes principales" *(ACP)* que asume que es posible explicar el 100% de la varianza observada.[64]

El método de componentes principales persigue como objetivo transformar un conjunto de variables originales en nuevos conjuntos de variables (sin perder información), combinación lineal de las variables originales, denominados componentes principales. El ACP permite pasar a un nuevo conjunto de variables los componentes principales que gozan de la ventaja de estar inter-correlacionados entre sí y que, además, pueden ordenarse de acuerdo con la información que llevan incorporada. Desde el punto de vista de su aplicación, el método de componentes principales es un método de reducción de datos, es decir, un sistema que permite reducir la dimensión del número de variables que inicialmente se han estimado.[57]

Para medir la cantidad de información contenida en un componente se utiliza la varianza, de modo que cuanto mayor sea su varianza, mayor es la información integrada en dicho componente. Por esta razón se selecciona como primer componente aquél que tenga mayor varianza, mientras que, por el contrario, el último es el de menor varianza.[48]

En el análisis de componentes principales o ACP, el primer factor o componente sería aquel que explica una mayor parte de la varianza total, el segundo factor, el que explica la mayor parte de la varianza restante (no explicada por el

primero) y así sucesivamente. De este modo sería posible obtener tantos componentes como variables originales.[57,64]

III. Paso: rotación de la solución:

La interpretación de los resultados del análisis factorial se basa en el análisis de las correlaciones entre las variables y los factores que viene dado por las cargas factoriales. Para que un factor sea fácilmente interpretable debe contar con las siguientes características: *1)* los coeficientes factoriales deben ser próximos a 1. Así las variables con cargas próximas a 1 se explican en gran parte por el factor, mientras que las que tengan cargas próximas a 0 no se explican por el factor; *2)* una variable debe tener coeficientes elevados en un solo factor y *3)* no deben existir factores con coeficientes similares.[44,57]

Así, si con la solución inicial no se consigue una fácil interpretación de los factores, éstos pueden ser rotados de manera que cada una de las variables verifique una correlación lo más próxima a 1 con un factor y a 0 con el resto de los factores. Como hay menos factores que variables, conseguiremos que cada factor tenga una correlación alta con un grupo de variables y baja con el resto. Si examinamos las características de las variables de un grupo asociado a un factor, es posible encontrar rasgos comunes que permitan identificar el factor y otorgarle una denominación que responda a dichos rasgos. Así conseguiremos desvelar la naturaleza de las interrelaciones existentes entre las variables originales.[44,57]

Los tipos de rotación más comunes son la ortogonal y la oblicua.[62,63] La rotación ortogonal permite rotar los factores estimados inicialmente de manera que se mantenga la correlación entre los mismos. El método más utilizado es el de Varimax, ideado por Kaiser[62,63] el cual consigue que cada componente rotado presente correlaciones únicamente con unas cuantas variables y es adecuado cuando el número de

componentes es reducido (como ocurre en el test diseñado en el presente estudio).[62-64] Sin embargo, la rotación oblicua no mantiene la ortogonalidad de los factores, lo que nos lleva a aceptar que dos o más factores expliquen a la vez una misma realidad. [62,63]

IV. Paso: estimación e interpretación de las puntuaciones:

Una vez estimados los factores comunes, es importante calcular las puntuaciones de los sujetos (individuos u objetos) investigados para saber cuánto ponderan en cada factor. De este modo podremos: *a)* Sustituir los valores de las variables originales para cada sujeto de la muestra por las puntuaciones factoriales obtenidas. En la medida en que el número de factores es menor que el número de variables iniciales, si el porcentaje de explicación de la varianza total fuese elevado, dichas puntuaciones factoriales podrían reemplazar a las variables originales en muchos problemas de análisis o predicción.[44] Además, numerosas técnicas estadísticas se ven seriamente afectadas por la correlación entre las variables originales. Si las puntuaciones factoriales están inter-correlacionadas, podrán utilizarse en análisis ulteriores. *b)* Colocar a cada sujeto en una determinada posición en el espacio factorial y conocer qué sujetos son los más "raros" o extremos (efecto de la puntuación del test en las variables del estudio); dónde se ubican ciertos grupos de la muestra (los más jóvenes frente a los mayores, los de mayor nivel de formación con los no formados, etc.); obteniendo en qué factores sobresalen unos y otros.[44,64]

Todos los pasos anteriormente expuestos pueden ejecutarse, entre otros, con el programa estadístico de análisis factorial del SPSS (Statistical Package for the Social Sciences / IBM Software v.20 - SPSS/PC+, Inc.; Chicago, IL, USA).[44]

4. JUSTIFICACIÓN

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En las últimas décadas, la investigación en nuestro campo se ha desarrollado con los objetivos primordiales de evaluar la adecuación y propiedades de los materiales dentales; el éxito, fracasos y complicaciones de los tratamientos odontológicos; así como profundizar en el estudio de las patologías; sin prestar apenas atención a otro tipo de variables que pudieran estar causando un impacto sobre el paciente y sobre el entorno en el que éste se desenvuelve.

En la actualidad se ha iniciado una nueva línea de investigación sobre el impacto en la calidad de vida relacionada a la salud oral que incluye, además de otro tipo de evaluaciones, el análisis de las preferencias de los pacientes, del efecto de los tratamientos sobre su bienestar general y de la satisfacción de los sujetos tratados.

Tradicionalmente, el estado de salud del paciente se ha asociado exclusivamente a las medidas objetivas aplicadas por el profesional. Probablemente, esta tendencia respondía a un intento de evitar la arbitrariedad de las valoraciones, atribuible a la posible subjetividad del paciente. Sin embargo, la psicometría ha demostrado que el término subjetivo no es sinónimo de arbitrario. Las medidas obtenidas pueden ser subjetivas y, sin embargo, carecer de errores, reflejando además una situación del paciente real y registrada adecuadamente. La salud oral percibida por la persona que se beneficia del tratamiento, es decir el propio paciente, gracias a las propiedades métricas de validez, fiabilidad y sensibilidad de los instrumentos que la miden, permite evaluar el estado funcional del sujeto con total garantía.

La investigación llevada a efecto en la presente Tesis Doctoral se centra en el estudio del impacto de los tratamientos protéticos en el paciente edéntulo. Este grupo poblacional, mayormente integrado por adultos mayores, no tuvo acceso a la filosofía

preventiva existente hoy en día. A ello se unen las características fisiológicas y los condicionantes económicos de estos sujetos, lo que subraya la importancia de realizar un seguimiento de su nivel de satisfacción tras la instauración de un tratamiento.

La triada "función, confort y estética" determina el éxito de un tratamiento protético. Las dos primeras propiedades pueden ser perfectamente objetivadas mediante el OHIP, tanto en su versión genérica como en su versión específica para pacientes edéntulos. Sin embargo, con respecto al tercer factor, los pacientes edéntulos presentan características peculiares, como cambios en el perfil facial y retrusión labial que les conduce a considerar la estética no sólo a un nivel intrabucal sino también teniendo en cuenta su aspecto perioral y facial. Cuando planteamos el protocolo del tercer artículo de esta Tesis Doctoral, no existía ningún tipo de medida que incluyera ítems concretos relativos a la estética en este tipo de pacientes.

Además, la OHRQoL está influida por numerosos factores externos como patología existente, tipo de prótesis, edad, experiencias previas, etc.; así como consideraciones adicionales de ámbito educativo, psicológico y socio-cultural, entre otras. Sin embargo, la mayoría de medidas de OHRQoL se ocupan de la recogida de impactos y no evalúan el posible efecto modulador de estas variables en el bienestar, dificultando por tanto las comparaciones.

En base a lo expuesto, la principal justificación de esta Tesis Doctoral fue profundizar en el conocimiento de la autopercepción de calidad de vida de pacientes edéntulos (totales y parciales) restaurados protéticamente, para poder determinar el impacto de nuestros tratamientos en su bienestar, y predecir, por tanto, el éxito de futuras rehabilitaciones en base al perfil socio-demográfico y a las características clínicas de los pacientes (ya que estas variables también fueron registradas para

cruzarlas con los resultados de los cuestionarios). Dicho conocimiento se alcanzó y aplicó mediante:

a) El estudio de usuarios de prótesis completa mucosoportada (tratamiento muy frecuente en la actualidad para estos sujetos, ya sea como medida a largo plazo o como prótesis de transición en rehabilitaciones implantológicas), para lo cual empleamos un índice genérico (OHIP-14sp).

b) El estudio de pacientes portadores de prótesis fijas sobre implantes, validando un índice específico para implantoprótesis (QoLIP-10) en usuarios de restauraciones fijas cementadas (único grupo para el cual aún no había sido validado).

c) El diseño de un nuevo índice (QoLDAS-9) para contemplar la "Calidad de vida asociada a la estética oral" ('OARQoL'), término acuñado por el grupo investigador para englobar todos los aspectos estéticos que pueden influir en la satisfacción del paciente con respecto al tratamiento prostodóntico.

Junto al QoLIP-10, el nuevo cuestionario permitirá al fin cubrir los tres conceptos clave en el éxito de una rehabilitación en pacientes no dentados: función, confort y estética; y evaluar el impacto del último en la calidad de vida. De este modo, podremos otorgar una dimensión aún más humana a nuestros tratamientos, tratando de objetivar, en lo posible, la subjetividad de nuestros pacientes.

5. OBJETIVOS

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Los principales objetivos de la investigación llevada a cabo en la presente Tesis Doctoral son los siguientes:

- Conocer las diferencias en cuanto al impacto del tratamiento protético sobre la calidad de vida relacionada con el estado de salud oral entre pacientes edéntulos portadores de prótesis completas convencionales mucosoportadas (a través de la aplicación del cuestionario genérico OHIP-14sp) teniendo en cuenta las características socio-demográficas, los factores relacionados con las prótesis y la condición clínica oral de dichos pacientes.

- Validar un cuestionario, corto, específico y eficaz para usuarios de prótesis cementada sobre implantes (QoLIP-10), examinando los factores externos que modulan la satisfacción del paciente subsidiario de este tipo de tratamiento.

- Diseñar y validar un cuestionario, corto, específico y eficaz que permita evaluar la calidad de vida asociada a la estética oral en pacientes edéntulos portadores de prótesis completas y sobredentaduras implantológicas, identificando las variables que condicionan la autopercepción estética de los pacientes.

- Ofrecer índices válidos, cortos y específicos al odontólogo restaurador para anticipar el efecto del tratamiento en la satisfacción y calidad de vida relacionada con la salud oral y la estética que percibirán los futuros pacientes en función de sus factores socio-demográficos y otras características clínicas y relacionadas con la propia prótesis. Estos instrumentos ayudarán a planificar la rehabilitación más adecuada.

6. METODOLOGÍA

Resumen metodológico

La presente Tesis Doctoral consta de tres estudios transversales retrospectivos desarrollados de acuerdo con los principios éticos de investigación médica en seres humanos recogidos en la Declaración de Helsinki de la Asociación Médica Mundial (http://www.wma.net) y la ley Española 14/2007 de 3 de julio que regula la investigación biomédica (http://www.boe.es). Asimismo, para la realización de estos trabajos de investigación se obtuvo la aprobación del Comité Ético del Hospital Universitario Clínico San Carlos de Madrid (C.E.I.C.; códigos de aprobación: C.I. 12/240-E, C.I. 12/241-E, C.I. 12/242-E, C.I. 12/280-E, C.I. 14/138-E y C.I. 14/139-E) (Anexo 10.1). Antes de participar en el estudio, todos los pacientes fueron informados sobre el propósito y el procedimiento de la investigación y se obtuvo su consentimiento informado firmado, según el modelo que figura en el correspondiente anexo (Anexo 10.2).

El procedimiento para recabar los datos de los sujetos de estudio fue común en las tres investigaciones y se diferenciaban dos fases. En la primera, se procedió a completar los cuestionarios correspondientes a cada estudio, siendo el investigador el que formulaba las preguntas. Los cuestionarios utilizados fueron el OHIP-14sp (Anexo 10.3), OHIP-20sp (Anexo 10.4), QoLIP-10 (Anexo 10.5) y QoLDAS-9 (Anexo 10.6). En los resúmenes de los artículos se especifican los que fueron utilizados en cada caso. Para mantener la confidencialidad del paciente, los cuestionarios fueron vinculados por medio de un código de identificación único para cada participante. En la segunda fase, se realizó un examen clínico de cada paciente, empleando la metodología de diagnóstico recomendada por la O.M.S.[65] para capturar los posibles factores moduladores de la OHRQoL.

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Oral health-related quality of life in complete denture wearers depending on their socio-demographic background, prosthetic-related factors and clinical condition

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Abstract

Objectives: To investigate the differences in impact on oral health-related quality of life (OHRQoL) among complete denture wearers depending on their socio-demographic characteristics, prosthetic-related factors and oral status.

Study Design: 51 patients aged 50-90 years treated, from 2005 to 2010, with at least one complete denture at the Department of Buccofacial Prostheses of the Complutense University (Madrid) were enrolled in this cross-sectional study. All of the participants answered the Oral Health Impact Profile (OHIP-14sp) questionnaire. The additive scoring method was used. The prevalence of impacts was calculated by using the occasional threshold (OHIP-14sp score≥2). Socio-demographic and prosthetic-related variables were gathered. Patients underwent clinical examination to assess their oral condition. Descriptive probes and Chi-Square tests were run ($p \leq 0.05$).

Results: The predominant participants' profile was that of a man with a mean age of 69 years wearing complete dentures in both the maxilla and the mandible. The prevalence of impact was 23.5%, showing an average score of 19±9.8. The most affected domains were "functional limitation" and "physical pain", followed by "physical disability". Minor impacts were recorded for the psychological and social subscales ("psychological

discomfort", "psychological disability", "social disability" and "handicap"). The prosthesis' location significantly influenced the overall patient satisfaction, the lower dentures being the less comfortable. Having a complete removable denture as antagonist significantly hampered the patient satisfaction. Patients without prosthetic stomatitis and those who need repairing or changing their prostheses, recorded significantly higher OHIP-14sp total scores. Conclusions: The use of conventional complete dentures brings negative impacts in the OHRQoL of elderly patients, mainly in case of lower prostheses that required reparation or substitution, with a removable total denture as antagonist. The prosthetic stomatitis in this study was always associated to other severe illness, which may have influenced the self-perceived discomfort with the prostheses, as those patients were daily medicated with painkillers.

Key words: *Oral Health Impact Profile (OHIP), oral health-related quality of life (OHRQoL), patient satisfaction, complete denture, elderly patients.*

Introduction

Notwithstanding the long-term success of implant-based restorations, the world population growth rates along with the extended life expectancy may lead to an increasing demand for conventional removable dentures. Moreover, this treatment modality allows avoiding surgical risks, difficulties and costs associated with implant prostheses (1). The complete edentation influences the well-being and life satisfaction of individuals (2). Also the use of conventional full dentures could have adverse effects on their oral health-related quality of life (OHRQoL). Although several instruments have been developed to assess the functional, social and psychological outcomes of oral disorders by using a methodological approach (3,4), there is no specific application to assess the impact of conventional dentures in OHRQoL. Nonetheless, using a generic health status scale may enable to compare more easily the results (5), which will prove the removable prostheses' real effectiveness in restoring the oral function taking also into account the patients' subjectivity when they express their feelings.

In 1994, Slade and Spencer (6) introduced the Oral Health Impact Profile (OHIP-49) questionnaire, containing 49 questions that capture seven conceptually formulated dimensions ("functional limitation", "physical pain", "psychological discomfort", "physical disability", "social disability" and "handicap"), based on the Locker's theoretical model of oral health (7). Despite its wide acceptance, proven reliability and strong validity, the large number of items included in this instrument may limit its use in clinical trials, clinical practice and surveys (8). When choosing measurement scales to evaluate the OHRQoL in the elderly, short questionnaires seem to have more advantages (9). Accordingly, in 1997, Slade (10) published a short form with the same dimensions (OHIP-14) that confirmed comparable results to those achieved with the original version of the OHIP. Furthermore, as any study based on questionnaires must take into account the socio-demographic characteristics of the population, translating and validating these assessment tools in different languages are required to consider the possible influence of socio-cultural factors on the self-perception of oral health (11).

This is the first study focused on the overall satisfaction of edentulous patients treated with conventional dentures after the OHIP-14 scale was validated for Spanish inhabitants (12). The information obtained may be useful in predicting with some caution the impact of this type of rehabilitation in the quality of life of patients from Spain and other countries that have related socio-demographic, cultural and clinical features. Therefore, the purpose of this investigation is to evaluate the differences in impact on OHRQoL among elderly complete denture bearers, using the Oral Health Impact Profile (OHIP-14) indicator.

Material and Methods

-Study protocol

The reference population was 118 patients aged 50-90 years treated, between 2005 and 2010, with at least one conventional complete denture at the Department of Buccofacial Prostheses of the Complutense University of Madrid. The exclusion criteria were: cognitive impairment, motility disorders and serious illness. 62 patients were invited by telephone to take part in the study. Each of the 51 final volunteers was scheduled for an appointment that consisted of an interview and a clinical examination free of charge. The Approval Ethics Committee (C.E.I.C., San Carlos University Hospital, Madrid. C.P. - C.I. 12/240-E) was obtained, as the study was conducted following the ethical principles of medical investigation involving human subjects under the Helsinki Declaration of the World Medical Association (http://www.wma.net) and the Spanish Law 14/2007 of July 3rd for Biomedical Research (http://www.boe.es). All of the participants were informed of the aims and procedures of the study. The patients' approved written consent was requested and confidentiality was maintained.

First of all, subjects completed a questionnaire supplying information on their socio-demographic background (age, gender, marital status, education level) and behavioral factors (smoking and drinking habits) (Group 1 of study variables).

Afterwards, the assessment of the technical conditions

of the prostheses was performed by a single researcher. The following denture-related data were registered: date of installation of the prosthesis, location and type of opposite prosthetic treatment (Group 2 of study variables). The diagnosis of the patients' oral health status was carried out by the same clinician. Time of edentulism, mobility of the masticatory mucosa, type of alveolar ridge, presence of prosthetic stomatitis, dry mouth sensation and need of treatment were recorded (Group 3 of study variables).

Four categories were established to classify the type of residual ridge that supported the complete removable prosthesis: Type 1: high wide ridge; type 2: high narrow ridge; type 3: low wide ridge; and type 4: low narrow ridge. Chronic inflammation of the denture-bearing mucosa, which was detected by direct visual inspection, was considered as "prosthetic stomatitis" (13). The requirement of treatment could involve medical management and control of oral lesions and/or repairing or changing the prostheses.

Participants that had worn previous complete dentures were asked about changes in their aesthetic appearance and chewing ability (better, worse, or equal) since they began using the prostheses analyzed in the present study.

Finally, the OHRQoL was assessed using the OHIP-14-sp (Spanish validated version of the OHIP-14 generic indicator) (12). A trained examiner applied the questionnaire in the form of a face-to-face interview. The volunteers answered in terms of frequency the appearance of 14 situations of impact conceptually divided into seven domains or dimensions. Each response was codified with one of the following options of a five-point Likert scale: "never" (score 0), "hardly ever" (score 1), "occasionally" (score 2), "fairly often" (score 3) and "very often" (score 4). To minimize the response bias a 1-month recall period was considered. The OHIP-14 outcome variable may range from 0 to 56 points, such that the lower the total score was, the minor impact on OHRQoL was and, thus, the greater the satisfaction and well-being of the patient were.

-Data analysis

All data analyses were made by using the Statistical Package for the Social Sciences (SPSS/PC+ v.19, Inc.; Chicago, IL, USA). In order to calculate not only the total OHIP-14sp output, but also the score per dimension, the additive method (OHIP-ADD) was used by adding (a) the scores recorded for the 14 items of the test and (b) the scores obtained for the two questions of each domain. The prevalence of impact was calculated by using the occasional threshold (score ≥ 2). Thus, a subject was considered with impact, if at least one item of the OHIP-14 was reported in and occasional or more frequently manner (score ≥ 2).

Descriptive statistics were calculated for all of the socio-demographic, prosthetic and clinical variables. Due to the fact that the Kolmogorov-Smirnov test confirmed that the OHIP-14sp outcome did not follow a normal distribution, the prevalence of impact on OHRQoL was compared between groups using the Chi Square test. A p-value < 0.05 was considered as statistically significant.

Results

-Analysis of socio-demographic, prosthetic and clinical variables

From the reference population (n = 118), 67 patients (56.78%) were excluded because of cognitive impairment (n = 1) or contact impossibility due to changes in their phone number and/or address details (n = 55 patients). A total of 11 patients refused to participate (rejection rate = 9.32%). The final pool of patients comprised 51 individuals. The most relevant statistical outcomes are shown in tables 1,2,3. Relating to the socio-demographic and behavioral variables (Group 1), the study sample was drawn mainly from men (70.6%), with a predominant age range of 65-74 years (43.1%), married (76.5%) and with a basic level of education (78.4%). Moreover, most participants were non-smokers (82.3%) and non- drinkers (74.5%) (Table 2).

Concerning the denture-related factors (Group 2), 82.4 % of the patients had worn their prostheses for a period of less than five years and 76.5% of the volunteers wore their complete dentures in the maxilla. The antagonist prosthetic treatment was a complete removable prosthesis (49%), an implant-retained overdenture (43.1%), a removable partial prosthesis (5.9%) or an implant-supported fixed denture (2%) (Table 3).

Regarding the clinical variables (Group 3), the mean time of edentulism was 15.5 ± 13.1 years. The masticatory mucosa presented mobility in 56.9% of cases. Sorted in descending order of frequency, 58.8% of the patients had a high wide ridge supporting the tested prostheses (type 1), 23.5% had a low wide ridge (type 3), 11.8% had a high narrow ridge (type 2) and 5.9% had a low narrow ridge (type 4). Prosthetic stomatitis was found in 5.9% of patients, whereas 21.6% of the participants reported a dry mouth sensation. 80.4% of the patients did not require any prosthetic-related treatment. 13.7% of participants needed repairing or changing their prostheses, whereas 5.9% of the volunteers required medical management of their oral lesions (Table 3, Fig. 1).

Prevalence of impacts (OHIP-14sp)

No questionnaires had to be eliminated from the study because all of the items were properly filled out in each case. Table 1 shows the most prevalently affected OHIP subscales. 23.5% of the participants reported at least one impact in an occasional or more frequently manner during the last month (Table 1). The average OHIP-14sp total score was 19 ± 9.8.

In view of the occasional threshold (score ≥ 2), the most affected dimensions or domains (D) were "functional

Table 1. Prevalence of impact on OHRQoL according to the domains and questions of the OHIP-14sp scale.

Question		Dimensions: n (%) of respondents					Subjects suffering from impact on OHRQoL (whatever score ≥ 2)	
Possible responses		Never	Hardly ever	Occasionally	Fairly Often	Very often	n	%
Response code		0	1	2	3	4		
D1. Functional limitation							12	23.5
Q1.	Trouble pronouncing words	45 (88.2)	0 (0.0)	6 (11.8)	0 (0.0)	0 (0.0)		
Q2.	Worse taste	36 (70.6)	7 (13.7)	1 (2.0)	3 (5.9)	4 (7.8)		
D2. Physical pain							8	15.7
Q3.	Sore spots	44 (86.3)	4 (7.8)	0 (0.0)	3 (5.9)	0 (0.0)		
Q4.	Discomfort (with dentures)	39 (76.5)	6 (11.8)	2 (3.9)	1 (2.0)	3 (5.9)		
D3. Psychological discomfort							4	7.8
Q5.	Worried	36 (70.6)	11 (21.6)	2 (3.9)	0 (0.0)	2 (3.9)		
Q6.	Tense	50 (98.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)		
D4. Physical disability							6	11.7
Q7.	Unsatisfactory diet	45 (88.2)	2 (3.9)	2 (3.9)	2 (3.9)	0 (0.0)		
Q8.	Interrupted meals	41 (80.4)	6 (11.8)	0 (0.0)	2 (3.9)	2 (3.9)		
D5. Psychological disability							4	7.8
Q9.	Interrupted sleep	34 (66.7)	13 (25.5)	2 (3.9)	2 (3.9)	0 (0.0)		
Q10.	Been embarrassed	45 (88.2)	4 (7.8)	0 (0.0)	2 (3.9)	0 (0.0)		
D6. Social disability							4	7.8
Q11.	Irritable with others	49 (96.1)	0 (0.0)	0 (0.0)	2 (3.9)	0 (0.0)		
Q12.	Having difficulty doing jobs	45 (88.2)	2 (3.9)	2 (3.9)	2 (3.9)	0 (0.0)		
D7. Handicap							2	3.9
Q13.	Unsatisfying life	49 (96.1)	0 (0.0)	0 (0.0)	2 (3.9)	0 (0.0)		
Q14.	Unable to function	51 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Total prevalence of impact							12	23.5

Q: Question; D: Dimension.

limitation" (23.5% of prevalence) and "physical pain" (15.7%) followed by "physical disability" (11.7%). Minor prevalence was recorded for the psychological and social subscales. Thus, the frequency of "psychological discomfort", "psychological disability" and "social disability" was 7.8%, whereas the "handicap" dimension resulted in a prevalence of 3.9% (Table 1).

Detailing the analysis of the OHIP scores obtained per question (Q), all of the participants reported "no impact" for being tense (Q6, D3) or feeling unable to function (Q14, D7). The main problems were found in worse taste (Q2, D1), which occurred occasionally or more frequently in 15.7% of cases. Subsequently, trouble pronouncing words (Q1, D1) and discomfort with dentures (Q4, D2) showed a prevalence of 11.8%. Intermediate values were found for feeling worried (Q5, D3), unsatisfactory diet (Q7, D4), interrupted meals (Q8, D4), interrupted sleep (Q9, D5) and experiencing some difficulties doing jobs (Q12, D6); all of them being reported by 7.8% of the patients. Minor prevalence of impact (5.9%) was registered for sore spots (Q3, D2). Finally, being embarrassed (Q10, D5), being irritable with others (Q11, D6) and having an unsatisfying life (Q13, D7), showed a prevalence of 3.9% (Table 1, Fig. 2).

The following modulating factors resulted in the highest prevalence of impact in quality of life (OHIP-14sp score ≥ 2):

Group 1: males (72.2%), within an age range of 50 to 64

Table 2. Prevalence of impact on OHRQoL as regards the socio-demographic and behavioural variables.

Socio-demographic and behavioural variables *(Group 1)*		*p*-values	Subjects having impact on OHRQoL (whatever OHIP item score ≥ 2) Study sample (n = 51)	
Type of variables	**Distribution of variables (%)**		**Frequency (n)**	**Within-subgroup prevalence (%)**
Gender				
Female	29.4	*p = 0.192*	8	53.3
Male	70.6		26	72.2
Age				
50-64	23.5	*p = 0.336*	8	66.7
65-74	43.1		14	63.6
75-90	33.4		9	52.9
Marital status				
Without partner	23.5	*p = 0.117*	8	66.7
Married	76.5		20	51.3
Education level				
Basic	80.4	*p = 0.167*	27	67.5
High School	15.7		6	75
University	3.9		2	100
Smoking habits				
Non-smokers	82.3	*p = 0.211*	34	81
Smokers	17.7		8	88.9
Drinking habits				
Non-drinkers	74.5	*p = 0.629*	21	55.3
Drinkers	25.5		9	69.2

$p > 0.05$: indicates the absence of significant outcomes in the prevalence of impact between subgroups.

years (66.7%), without partner (66.7%), having university education (100%) and being smokers (88.9%) and drinkers (69.2%) (Table 2). However, no significant differences were recorded for such socio-demographic and conductual variables.

Group 2: wearing the prosthesis for less than 5 years (71.4%), having a full lower denture (75%) and an opposite complete denture (92%) (Table 3). The prosthesis' location significantly influenced the patient overall satisfaction, the lower dentures being the less comfortable ($p = 0.026$). Furthermore, the "functional limitation" and "physical pain" dimensions showed significantly higher prevalence of impact in patients who wore lower complete dentures ($p < 0.01$). Significant differences were found depending on the type of opposite prosthetic treatment ($p = 0.042$), so that opposing complete removable dentures resulted in the lower patient satisfaction ($p < 0.05$) (Table 3).

Group 3: being edentulous for less than 5 years (69.2%), having mobility of the masticatory mucosa (65.5%) and low-wide-shaped ridges supporting the denture (50%), absence of prosthetic stomatitis (70.8%), patients reporting dry mouth sensation (63.6%) and needing reparation of their complete prostheses (85.7%).

Significantly lower prevalence of impact was achieved for patients with prosthetic stomatitis ($p = 0.012$) and for those who required reparation or substitution of their conventional prostheses ($p < 0.05$) (Table 3).

Although no significant differences were recorded, participants reporting a dry mouth sensation showed a trend of attaining higher prevalence of impact on the "physical pain" dimension (53%).

In addition, whereas all of the volunteers that had worn previous prostheses (78%) experienced aesthetic improvements since they wore the tested dentures, 64.3% of them noticed positive changes in their chewing ability.

Table 3. Prevalence of impact on OHRQoL as regards the oral health-related variables.

Prosthetic and oral health-related variables. Study sample (n = 51).				
Type of variables	**Distribution of variables (%)**	***p*-values**	**Subjects having impact on OHRQoL (whatever OHIP item score ≥ 2)**	
Denture-related variables *(Group 2)*			**Frequency (n)**	**Within-subgroup prevalence (%)**
Date of installation of the prosthesis				
From 0.25 to 5 years	82.4	*p = 0.991*	30	71.4
From 6 to 10 years	11.8		4	66.7
From 11 to 15 years	5.8		2	66.7
Location				
Maxilla	76.5	* *p = 0.026*	8	20.5
Mandible	23.5		9	75
Opposite prosthetic treatment				
Complete removable prosthesis	49	* *p = 0.042*	23	92
Removable partial prosthesis	5.9		1	33.3
Implant-retained overdenture	43.1		10	45.4
Implant-supported fixed prosthesis	2		0	0
Clinical variables *(Group 3)*		***p*-values**	**Frequency (n)**	**Within-subgroup prevalence (%)**
Time of edentulism				
< 5 years	25.5	*p = 0.293*	9	69.2
6 to 20 years	54.9		15	53.6
> 20 years	19.6		4	40
Mobility of the masticatory mucosa				
Yes	56.9	*p = 0.842*	19	65.5
No	43.1		10	45.4
Type of ridge				
High wide	58.8	*p = 0.140*	6	20
High narrow	11.8		2	33.3
Low wide	23.5		6	50
Low narrow	5.9		1	33.3
Presence of prosthetic stomatitis				
Yes	5.9	* *p = 0.012*	0	0
No	94.1		34	70.8
Dry mouth sensation				
Yes	21.6	*p = 0.630*	7	63.6
No	78.4		18	45
Need of treatment				
Need of medical management of oral lesions	5.9	* *p = 0.04*	1	33.3
Need of repairing or changing the prostheses	13.7		6	85.7
No treatment was required	80.4		10	24.4

*: implies significant differences in the prevalence of impact between subgroups.
p > 0.05: indicates the absence of significant differences.

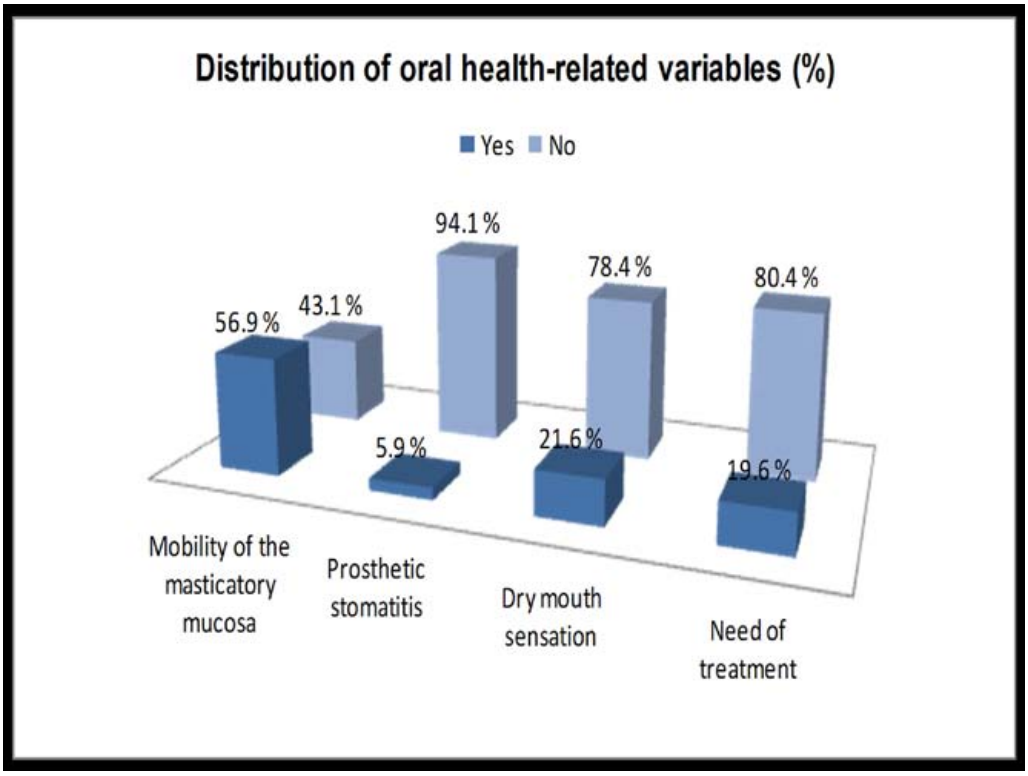

Fig. 1. Distribution of oral health-related variables in the study sample (%).

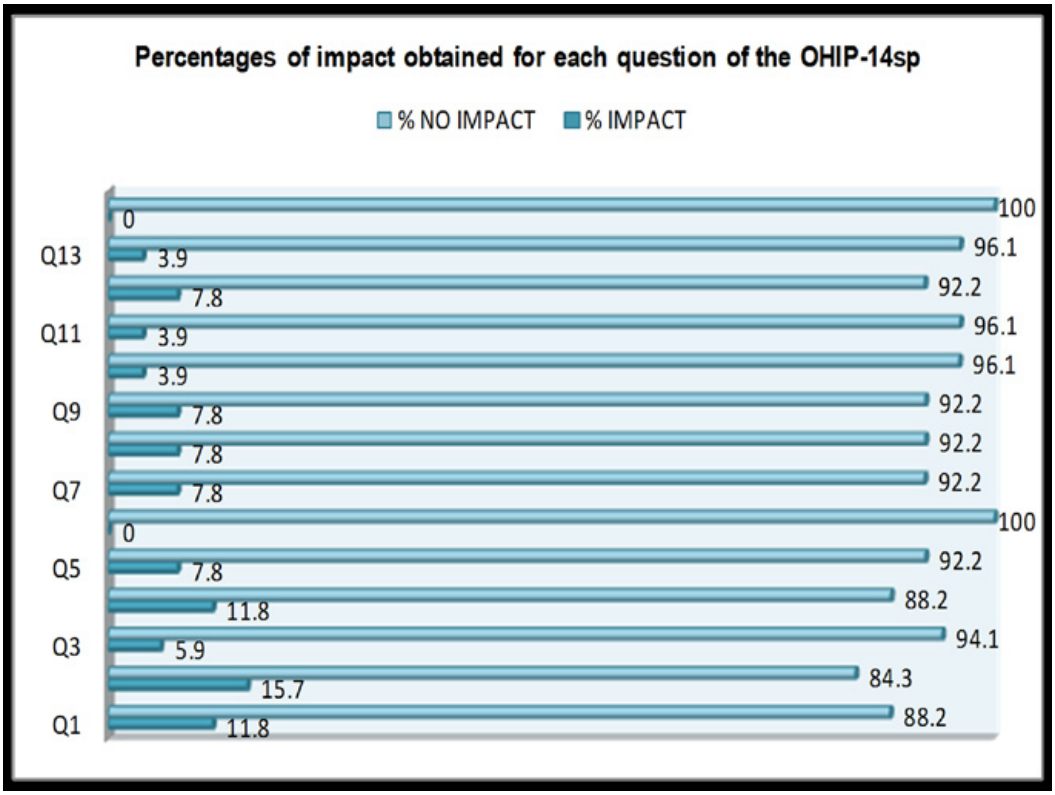

Fig. 2. Percentages of impact obtained for each question of the OHIP-14sp. The 14 items of the questionnaire are grouped in the next dimensions/ domains: "functional limitation" (Q1 and Q2); "physical pain" (Q3 and Q4); "psychological discomfort" (Q5 and Q6); "physical disability" (Q7 and Q8); "psychological disability" (Q9 and Q10); "social disability" (Q11 and Q 12); "handicap" (Q13 and Q14).

Discussion

This paper describes the general satisfaction of conventional complete denture wearers on the basis of cross-sectional survey-based data and clinical examination. The sample size was similar to that of related studies on the influence of prosthetic rehabilitations in OHRQoL (14). The results obtained may help predict the possible effect of conventional prostheses in terms of the well-being of future patients. Although one limitation of the research protocol is that the participants were recruited only from a university dental clinic, due to the variability in the gender, age, marital status, level of education and behavioural habits of the volunteers (Fig. 1), our findings might be indicative for patients from other countries having comparable socio-demographic and clinical profiles. Nevertheless, the results of this study should be extrapolated with caution, taking into account that the sample size and the recruitment method may hamper their worldwide application.

The Oral Health Impact Profile generic scale has demonstrated better performance than other questionnaires (15) and higher sensitivity to detect dissatisfaction. It has previously been applied in clinical trials and cross-sectional studies to evaluate the effectiveness of treatments for edentulism (5,16). The use of the OHIP in the present investigation facilitated the comparison of the results. For the same reason, the occasional threshold, which considers as impact responses those scored ≥ 2 (12,17), was chosen. The Spanish validated version of the OHIP-14 (12) was applied in the interview format. Whereas Souza et al. (18) reported no scoring differences regarding the form of administration (self-completed *vs.* interview), Ekanaye and Perera (2) found lower completion rates and loss of data when the OHIP-14 was self-filled.

A one-month recall period was considered to report impacts instead of a twelve-month recall period that was used in the original source (6). Even though John et al. (19) confirmed that the remind period did not affect the internal consistency of the OHIP, short-term memory is expected to be more accurate to provide a reliable information (2).

The prevalence of impact obtained in this study (23.5%) (Table 1), which is the percentage of subjects reporting at least one item affected in an occasional or more frequently manner (scored ≥ 2), is less than one third of that previously reported for the Spanish population (12,17). However, it is meaningful that, unlike what happened in such studies, our patients were older and not seeking any treatment. It has been reported that the higher the age, the more frequent the impacts, which has been attributed to the accumulative kind of the oral pathology, such as tooth decay or periodontal disease (17). However, the present investigation was performed on edentulous patients, which may explain to some extent the absence of direct correlation between age and oral impact prevalence. Concerning the OHIP-14sp total average score obtained (19 ± 9.8), Emami et al. (20) suggested that, although mandibular implant-retained overdentures may be more satisfying for edentulous patients than new conventional dentures, the magnitude of the effect still remains to be ascertained. Therefore, there is a need for additional evidence including cost-effectiveness analyses on the impact of mandibular implant overdentures and conventional prostheses.

With regard to the major prevalence of impact, it was found that "functional limitation" (D1) and "physical pain" (D2) were the main causes behind the general patients' concern, being responsible for worse taste (Q2) followed by trouble pronouncing words (Q1, D1) and unpleasant sensations with dentures (Q4, D2), which were the most common problems included in such dimensions. "Physical disability" (D4) was the third most affected domain, revealing marked diet dissatisfaction (Q7) and interrupted meals (Q8) (Table 1, Fig. 2). Alteration of taste and fear of losing the denture while eating or talking are consequence of the intrinsic limitations of the complete denture treatment, such as low masticatory performance, compromised retention and stability and coating of palatal minor salivary glands (18). De Oliveira and Frigerio (21) reported that complete denture users could be even more susceptible to malnutrition when compared to implant-retained overdenture wearers.

"Psychological discomfort", "psychological disability" and "social disability" (D3, D5 and D6, respectively) were less prevalent for the occasional threshold. Complete denture bearers scarcely complained about feeling embarrassed (Q10, D5) or being irritable (Q11, D6) when they wore their prostheses. No participants referred getting nervous with their rehabilitations (Q6, D3). However, the highest incidence of the social domains corresponded to being worried (Q5, D3), having interrupted sleep (Q9, D5) and difficulty doing jobs (Q12, D6) (Table 1, Fig. 2). This reveals a positive perception for these domains; which agrees with the trend observed by Slade and Spencer (6) when they used the original version of the questionnaire (OHIP-49). Concerning the segmented sleep, dentists generally recommend removal of dentures during the night, since constant wearing can increase the risk of irritations and infections. However, around 10% of people with obstructive sleep apnoea (OSA) who wear complete dentures may experience increased breathing difficulties if they sleep with their prostheses out. Recent findings suggest that in patients with OSA, the advantages of removing dentures during sleep should be weighted against the risk of worsening upper airway collapse (22). Therefore, this factor should be further evaluated by monitoring the patients to correlate the presence of OSA with the score obtained in the Q9 (D5) of the OHIP when patients sleep with or without their prostheses.

The "handicap" subscale (D7) disclosed the best over-

all satisfaction with the existence as a general concept (Q13) and the ability in the development of ordinary life (Q14) when patients used their conventional dentures. Thus, no patients in this research felt unable to function (Q14) (Table 1, Fig. 2). Additionally to the greater tolerance to disability of mature patients (23), it is likely that subjective, patient-related feelings have been the major deciding factors of satisfaction concerning this domain.

Gender yielded no significant differences in our study, although there seems to be a marked tendency to higher impact and lower satisfaction in men (Table 2). These data agree with the findings of Slade and Spencer in edentulous patients (6). Some authors stated the independence of this factor on the subjective perception of OHRQoL (17,23) whereas others reported opposite results (5,12). Therefore, the effect and magnitude of this variable should be further assessed. Besides, the age was not a modulating factor of OHRQoL in the present research (Table 2). This may be justified because of the reduced age range of the sample. Married patients tended to express higher overall satisfaction with their conventional dentures than those without partner, although no significant differences were encountered (Table 2). This issue requires further validation, as no previous related study analyzed this variable.

People with higher educational level showed a trend toward a higher impact in their quality of life with no significant differences with respect to those having basic education (Table 2). Such tendency was announced by McGracth and Bedi in the U.K. (23) and Montero et al. in Spain (17). Moreover, a slightly higher percentage of impact was found in smokers and drinkers (Table 2). Even though no significant differences were recorded, this tendency concurs with the findings of Lin et al. (24), who reported a higher incidence of oral lesions in smoker and drinker patients.

Being edentulous and wearing the denture for less than five years resulted in higher impacts, as it takes time for patients to get used to removable prostheses (Table 3). Full lower denture wearers confirmed significantly lower overall satisfaction (Table 3), which may be due to the centrifugal resorption pattern of the mandible that affects the osteomucosal support of the residual bridge (25). Consistently with Fenlon and Sherriff (26), subjects having a plane flange reported less satisfaction and higher impact in OHRQoL. This mainly occurred when the masticatory mucosa was mobile and not keratinized (Table 3), leading to lower resistance to trauma. Patients often express dissatisfaction with their mandibular prostheses, complaining about retention stability and difficulties with mastication and verbal communication (27). Accordingly, the "functional limitation" and "physical pain" dimensions showed significantly higher levels of impact when the complete dentures were located in the mandible.

Considering the antagonist prosthetic treatment, at one with Hogenius et al. (28), the lowest prevalence of impact in OHRQoL is characteristic of patients wearing implant-supported fixed prostheses, followed by removable partial dentures in the opposite jaw. Intermediate impact values were recorded when the antagonist was an implant-retained overdenture. The highest impact prevalence corresponded to patients wearing complete dentures in both the maxilla and the mandible, showing significant differences with the other subgroups (Table 3). Awad et al. (16) found that implant-based treatments significantly improved the health-related quality of life outcome when compared with conventional dentures.

Having a dry mouth sensation resulted in higher impact in patients' quality of life taking into account that saliva plays an important role in retention and comfort of removable prostheses. However, no significant differences were detected in the present study (Table 3). The dry mouth sensation has been associated with age and pharmacotherapy (29). In our investigation, patients who expressed dry mouth sensation were medicated for thyroid problems, sleepiness, hypertension, Parkinson, epilepsy or prostate cancer, among others.

Significant differences were identified depending on the presence of prosthetic stomatitis, so that patients with such disease showed no impact in OHRQoL (Table 3). In this research, prosthetic stomatitis was always associated to other severe illness, such as cancer. Thus, the self-perception of discomfort with the prostheses may have faded into the background in case of these patients. Moreover, all participants having severe illness in the present study were daily medicated with painkillers, which may reduce the impact of their prostheses in OHRQoL (29). However, the lack of studies correlating the presence of severe illness (resulting in diseases such as prosthetic stomatitis) and pharmacotherapy with the level of impact in OHRQoL makes comparisons difficult. Therefore, this issue should be further evaluated in different and larger populations to redefine this conclusion.

Patients who required repairing or changing their prostheses expressed significantly lower satisfaction (Table 3), as previously reported (14).

In this study, both the self-perceived aesthetic appearance and the chewing ability improved in most patients who had worn other conventional dentures. Such results are related to those obtained by using the OHIP-14sp, as chewing ability is one of the determinants of denture satisfaction best associated with OHRQoL (30).

To summarize, the following may be concluded: (1) Conventional complete dentures bring negative impacts in the OHRQoL of elderly patients, mainly concerning functional limitation and physical pain. (2) Maxillary conventional dentures are more comfortable than mandibular ones. (3) The overall patient satisfaction as regards OHRQoL is hampered by having a total removable prosthesis as antagonist. (4) The self-perceived discomfort with conventional dentures faded into the

background in patients with prosthetic stomatitis, who always suffered from other severe illness in the present study and were daily medicated with painkillers. (5) The requirement of repairing or changing the prostheses resulted in higher impact in OHRQoL.

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Validation of the 'Quality of Life with Implant Prostheses (QoLIP-10)' questionnaire for wearers of cement-retained implant-supported restorations

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ABSTRACT

Objectives: To validate the 'Quality of Life with Implant-Prostheses (QoLIP-10)' questionnaire for assessing the impact of cemented implant prostheses on Oral Health-Related Quality of Life (OHRQoL).

Methods: 84 subjects wearing implant restorations were distributed as follows: Group 1 (SD-I; $n = 35$): screwed FDPs (fixed dental prostheses) supported by 2 implants; Group 2 (SD-II; $n = 7$): screwed FDPs supported by 3–5 implants; Group 3 (CD-I; $n = 36$): cemented FDPs supported by 2 implants; and Group 4 (CD-II; $n = 6$): cemented FDPs supported by 3-5 implants. The QoLIP-10 and the Oral Health Impact Profile (OHIP-14sp) scales were used. Data related to global oral satisfaction, socio-demographics, health-behaviors, and prostheses, were gathered. Reliability and validity of the QoLIP-10 were investigated. Correlations between both indices were explored with the Spearman's rank test. Descriptive and non-parametric probes were run to evaluate the effect of the study variables on the OHRQoL ($\alpha = 0.05$).

Results: The QoLIP-10 confirmed its psychometric capacity for cemented implant prosthesis wearers. Both tests were inversely correlated. The QoLIP-10 attributed the significantly worst QoL to long-span cemented prostheses. Groups were significantly discriminated by the QoLIP-10 *performance* dimension. The variable *complaints about the mouth* and the *three global oral satisfaction* measures significantly modulated the OHRQoL.

Conclusions: Patient satisfaction depends upon the extension and the type of retention of implant FDPs.

Clinical significance: The QoLIP-10 may help estimating the effect of cemented FDPs on patients' well-being. When compared to screwed FDPs, short cemented implant restorations lead to greater improvements in patients' self-perceived QoL.

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1. Introduction

Clinical research activities in implant dentistry have mainly focused on the survival rates of the implants and on the longevity of the restorations.[1,2] Nonetheless, there are few studies assessing the Oral Health-Related Quality of Life (OHRQoL) of implant prosthesis wearers.[3,4,5,6] Although different generic scales have been used,[3,4,7–9] specific questionnaires are preferred to measure the impact of implant prostheses on the OHRQoL.[5,6]

In this respect, a new, short and precise index, called 'Quality of Life with Implant-Prostheses (QoLIP-10)'[5,6] has recently been developed. This 10-item scale, which contains three conceptual dimensions (*i.e.*, biopsychosocial, dental-facial aesthetics, and performance), is the only available specific instrument to assess the OHRQoL after implant-prosthetic treatment.[5,6] To date, this index has demonstrated its psychometric capacity in case of implant-retained overdentures, hybrid prostheses, and screwed implant restorations.[5,6]

This cross-sectional study is, therefore, the first to validate a specific OHRQoL scale (QoLIP-10) for wearers of cement-retained implant-supported FDPs (fixed dental prostheses). With this purpose, a generic scale with high sensitivity for detecting dissatisfaction with prosthetic rehabilitations (*i.e.*, the short validated version of the Oral Health Impact Profile: OHIP-14sp)[8,10] has also been applied in a retrospective fashion. Subjects with screw-retained implant prostheses have been included as controls based on their fixed connexion system.

Retrievability remains the main advantage of screw-retained restorations and, simultaneously, the major drawback of cement-retained implant FDPs. Nevertheless, cemented implant prostheses show noteworthy benefits, including simplification of implant restorative procedures, reduction of fabrication costs, passivity, and absence of screw access openings.[11–16] Regrettably, residual cement often results in peri-implant tissue inflammation, which may also impair patients' well-being.[11,15]

Screwing implant prostheses simplifies the periodic recovery of the superstructures for hygiene, repairs, and tightening the abutments' screws. However, the presence of occlusal screw holes may compromise the biomechanical behavior of the rehabilitation, affecting occlusion, porcelain strength and aesthetics, among others.[14]

Hence, the aim of this study is to investigate the psychometric properties of the QoLIP-10 questionnaire for assessing the OHRQoL of cement-retained implant prosthesis users and to determine the factorial construct of the patients' self-perceived satisfaction. This may help estimating the OHRQoL of future candidates for fixed implant therapy worldwide on the basis of the sample variability and the type of restoration to be performed.

The null hypotheses tested were that: (1) the type of retention of fixed implant restorations (cemented or screwed) does not affect the patient well-being; and that (2) the QoL (quality of life) of fixed implant prosthesis wearers does not depend on socio-demographic, health-behavioral, and/or prosthetic related variables.

2. Materials and methods

2.1. Study protocol: pilot trial and sampling procedure

Before beginning the main investigation, a pilot trial was conducted on a representative sample of patients, who were recruited from the same source population. These patients numerically represented a percentage of 25.5% of the main study sample ($n = 84$).

It has been shown that ten patients (or even fewer) are sufficient to evaluate a questionnaire for precision, wording, formatting, and ease of administration.[17] Given the population variability in this study,[17,18] twenty-two volunteers were selected for the pilot trial. The participants met selection criteria that were similar to those of the patients of the main investigation. They wore screwed FDPs supported by two or three implants (31.4%, $n = 11$), and cemented FDPs supported by two or three implants (30.5%, $n = 11$).

This trial allowed to empirically check the face and content validities of the QoLIP-10 scale[5,6,17,18] in cement-retained implant prosthesis wearers. The valid version of the index for screwed prosthesis wearers (which was the one selected for the study)[6] was evaluated by asking the volunteers about the clarity of the questionnaire. This procedure guaranteed the validity of the index to be applied in the main cross-sectional research.[17,18]

The main sample was initially composed of 105 subjects over 18 years old, all of whom had been treated with one screwed restoration or one cemented restoration (supported by 2–5 implants in either case) at the Department of Buccofacial Prostheses of the Complutense University of Madrid (U.C.M., Spain). Subjects were invited to take part in the study when they attended the clinic for a yearly routine exam in 2014, between April and September. Patients who agreed to be interviewed were offered a clinical examination free of charge.

With regard to the exclusion criteria, patients were excluded based on serious illness, motility disorders, cognitive impairment, implant loss, implants received during the last year, demand for dental treatment, and/or presence of a removable antagonist (*i.e.*, a muco-supported complete denture, a removable dental prosthesis, an implant-retained overdenture, or a fixed-detachable hybrid prosthesis) to avoid misinterpretation of the findings. Mainly due to the inclusion of two partially dentate groups, the presence of an opposing occlusal plane of natural teeth or fixed tooth-supported prostheses was required.

The 84 final volunteers were scheduled for appointments in October 2014. The subjects were assigned to the following groups depending on the type of implant restoration worn by the patient: Group 1 (SD-I; $n = 35$): metal-ceramic screwed FDPs supported by 2 implants (control 1); Group 2 (SD-II; $n = 7$): metal-ceramic screwed FDPs supported by 3–5 implants (control 2); Group 3 (CD-I; $n = 36$): metal-ceramic cemented FDPs supported by 2 implants; and Group 4 (CD-II; $n = 6$): metal-ceramic cemented FDPs supported by 3–5 implants.

The study was conducted following the ethical principles of medical investigation involving human subjects under the Helsinki Declaration of the World Medical Association (http://

www.wma.net) and the Spanish Law 14/2007 of July 3rd for Biomedical Research (http://www.boe.es). All of the participants were briefed about the purpose and process of the study, and signed the consent document. The Ethics Committee Approval was obtained (C.E.I.C., San Carlos University Hospital, Madrid: C.I. 12/242-E, C.I. 12/280-E, C.I. 14/138-E, and C.I. 14/139-E). Confidentiality was maintained.

2.2. Data gathering

The volunteers completed the QoLIP-10 (validated version for screwed prosthesis wearers)[6] and the OHIP-14sp[10] aided by a trained interviewer who asked the questions.[5,6,10,19]

Originally, the QoLIP-10 was validated for evaluating the OHRQoL of patients restored with implant-retained overdentures and fixed-detachable hybrid prostheses.[5] Afterwards, the QoLIP-10 was adapted and validated for screwed implant prosthesis users; this version being the one utilized in this study.[6] The first factor of this latest version of the QoLIP-10, named *biopsychosocial dimension*, contains the Items 1, 3, 4, and 5 of the original QoLIP-10 index (oral pain, worry/concern, communication/social relations, and activities of daily living, respectively). The second factor, called *dental-facial aesthetics dimension* comprises the original Items 6, 7, and 8 (satisfaction with the prosthesis' appearance, satisfaction with the realism of the prosthesis, and satisfaction with the smile, respectively). The third factor, designated as *performance dimension*, includes the Items 2, 9, and 10 of the original questionnaire (chewing difficulty, speaking difficulty or restrictions, and oral hygiene difficulty, respectively).

The responses of the QoLIP-10 are intuitive and expressed on a Likert-type scale[20] with proportional codes for the degrees of impact. Items evaluated as <0 are considered to have a negative effect, while values evaluated as +1 and +2 represent the positive side of each item (or at least the absence of a negative effect). The possible responses were: 'strongly disagree' (score −2), 'disagree' (score −1), 'indecisive, indifferent, or neutral' (score 0), 'agree' (score +1), and 'strongly agree' (score +2). The total or summary score was the sum of the different item scores, so that negative and positive impacts contributed to the total net score (*i.e.*, the additive scoring method: ADD).[21] The total score of the QoLIP-10 questionnaire can range from −20 to +20 in such a way that the higher the summary score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer self-perceived quality of life).[5]

Participants also completed the 14-item Oral Health Impact Profile (OHIP-14sp) measure, which has been described in detail elsewhere.[8,10] Subjects filled out the OHIP-14sp answering in terms of frequency the appearance of 14 situations of impact that were conceptually divided into seven dimensions (*i.e.*, *functional limitation*, *pain*, *psychological discomfort*, *physical disability*, *psychological disability*, *social disability*, and *handicap*). Frequency was also codified using a classic Likert-type Scheme[20] with five options. In this case, the possible impact responses were: 'hardly ever' (score 1), 'occasionally' (score 2), 'fairly often' (score 3), and 'very often' (score 4). The 'never' response (score 0) revealed the absence of impact. The OHIP-14sp outcome variable ranged from 0 to 56. On this scale, the higher the total score is, the higher the level of negative impact on patients' well-being is, so that higher scores imply lower QoL and patient satisfaction.[10]

Participants reported their overall satisfaction with their mouths, including aesthetics, chewing, and prosthetic restorations.[22] A visual analogue scale (VAS)[6] was used for each of the abovementioned areas, so that these perceptions were assessed in a continuous range from 0 to 10. Subjects could thereby declare themselves to be 'dissatisfied', 'neutral', or 'satisfied', offering values situated left to the midpoint of a 100-mm long line, on the midpoint, or right of the midpoint, respectively.[6,23]

A different investigator conducted each type of questionnaire. To ensure that the clinic staff had no access to the patients' responses, the completed forms were placed in sealed envelopes. The QoLIP-10, OHIP-14p, and VAS evaluations were then linked by means of a unique identification code for each study patient.[5,6,22]

To capture the clinical modulating factors, subjects were examined by a single researcher using the diagnostic methodology published by the World Health Organization (WHO).[24] The study variables were grouped as follows: Group 1: Social-demographic variables (gender, age, marital status, and level of education); Group 2: Health behavioral variables (daily rate of tooth-brushing, and number of dental visits per year); and Group 3: Self-perceived satisfaction with the mouth and prosthetic-related data (complaints about the mouth, perception of the need for dental treatment, and status of the prosthesis).[6]

2.3. Statistical analysis

The additive method (–ADD)[10,23] was used for both the QoLIP-10 and OHIP-14sp analyses by adding the item codes at the appropriate frequency. The dimensional scores of each index were obtained using a similar procedure. All of the data collected were processed as explained below, according to statistical methods used in related research.[4–6,22,25]

Descriptive statistics[4,22,26] and percentages for qualitative and categorical variables were calculated.[5,6] The main psychometric capacity (reliability and validity)[22] of the QoLIP-10 questionnaire was tested in cement-retained implant prosthesis wearers. As each item measured different aspects of the same attribute, the reliability was assessed by examining the internal consistency of the scale through the use of an inter-item correlation, item-total correlation, Cronbach's alpha, and alpha value if an item was deleted.[5,6,27]

The Kolmogorov–Smirnov test[4] did not assume a normal distribution of the QoLIP-10 outcome variable in the groups tested. Hence, the criteria validity of the QoLIP-10 indicator for cemented implant prosthesis wearers (which measures how well the test predicts the QoL based on information obtained from other variables)[27,28] was analysed by contrasting the total scores achieved in each of the QoLIP-10 and OHIP-14sp indices with the VAS scores, using non-parametric probes. Therefore, the Kruskal–Wallis test was applied for variables with three or more categories, and the Mann–Whitney *U* test was used for variables with two categories.[5,26,29]

The construct validity of the QoLIP-10 for cemented implant prosthesis wearers (or the extent to which the OHRQoL was actually recorded with this questionnaire)[27,28]

was investigated using factor analysis (*i.e.*, a data reduction technique that allows homogeneous subgroups of variables to be found), and the convergent validity of the scale (which measures how closely the new questionnaire is related to other variables and measures of the same construct to which it should be related).[18]

Regarding the factor analysis, the Bartlett's Sphericity and the Kaiser–Meyer–Olkin (KMO) tests, which are measures of sampling adequacy, were run to make evident the underlying factor structure of the QoLIP-10 index in cement-retained implant prosthesis wearers.[22] Additionally, the principal components' analysis (PCA) was performed along with the rotation method: the Varimax plus Kaiser normalisation was used to extract the underlying dimensions of the prosthetic construct.[30] The items were assigned to the rotated factors when they had a loading of 0.5 or greater in a single factor.[5,6]

Factors with an eigenvalue of less than one were disregarded to avoid distortion.[22] To establish the degree of convergent validity, the QoLIP-10 total and sub-scale scores were correlated to those of the OHIP-14sp scale using the Spearman's rank correlation test.[31]

To investigate the discriminant validity, the total and dimensional scores of both indices were compared among the prosthodontic groups using the Kruskal–Wallis test.[5,26,29]

After evaluating the psychometric properties of the QoLIP-10 for cemented implant prosthesis wearers, the influence of possible modulating factors were explored. Thus, the Kruskal–Wallis and the Mann–Whitney *U* tests[26] were run to evaluate and compare the influence of the study variables on the impact scores of both the QoLIP-10 and the OHIP-14sp questionnaires among the study groups.[4,22]

Data were processed using the Statistical Package for the Social Sciences (software v.20) (SPSS/PC+, Inc.; Chicago, IL, US), setting the statistical significance at $\alpha = 0.05$.[4–6,25,26]

3. Results

3.1. *Description of the sample*

A total of 21 (20%) patients were excluded from the reference population ($n = 105$). Nine of them could not be contacted because of changes in their phone number. The remaining twelve patients refused to participate due to time constraints (rejection rate = 11.4%). The final study sample comprised 84 individuals.

Socio-demographically (Group 1), most participants were female (57.1%, $n = 48$), aged more than 65 years (57.1%, $n = 48$), married (75%, $n = 63$), and had a basic education (46.4%, $n = 39$) (Table 1).

Concerning the health behavioral variables (Group 2), 50% of the subjects ($n = 42$) brushed their teeth twice a day, while 52.4% ($n = 44$) visited the dentist once a year (Table 1).

Most participants did not complain about their mouths (86.9%, $n = 73$), and did not perceive a need for dental treatment (77.4%, $n = 65$) (Group 3) (Table 1). Prosthetic-related data (Group 3) also revealed that 59.5% ($n = 50$) of the implant restorations were in good condition, while 19% ($n = 16$) required to be repaired, and 21.4% ($n = 18$) urged to be replaced (Table 1). In general, most participants were satisfied with their dental aesthetics (70.2%, $n = 59$), chewing functionality (72.6%, $n = 64$), and rehabilitation (72.6%, $n = 64$) (Table 1).

3.2. *Analysis of the reliability and validity of the QoLIP-10 questionnaire for cement-retained implant prosthesis wearers*

The reliability (or internal consistency) of the QoLIP-10 scale for cemented implant prosthesis wearers was supported by alpha values of 0.92 (direct values) and 0.91 (typical values) (Table 2). These results were significant ($p < 0.0001$); therefore, the reliability of the index was estimated to be within the interval of 0.35 to 0.48 with a 95% degree of confidence.

Furthermore, the QoLIP-10 total score was strongly correlated ($p < 0.001$) with all of its sub-scale scores (Table 3), whereas the OHIP-14sp total score was not significantly correlated with the scores of its *social disability* and *handicap dimensions* ($p > 0.05$) (Table 3).

An overall distribution of positive inter-item correlations was confirmed for the QoLIP-10 questionnaire and alpha values were lower or equal when either item was deleted. The inter-item correlation analysis showed that all of the coefficients were positive (ranging from 0.06 between Items 9 and 10, to 0.9 between Items 5 and 6). This fact revealed that the concept was measured in the same direction. Although most correlations were significant, none of them was intense enough to verify the existence of clear redundancy in content. All of the items showed satisfactory homogeneity with coefficients ranging from 0.59 to 0.93.

As all of the items and their possible responses were presented together in a matrix (which facilitates self-completion by patients), the face validity of the index was considered adequate in the pilot trial. Moreover, the participants declared that the items were comprehensible. Additionally, the Likert responses[20] had a symmetric format that allowed to be intuitively understood, as the range was demarcated by the most extreme positive and negative options. The QoLIP-10 also demonstrated satisfactory content validity for cement-retained implant prosthesis wearers. This questionnaire focuses on physical, psychological, and social activities that might be impaired by oral conditions. The study subjects did not mention any situation of impact that was not included in the questionnaire.

The QoLIP-10 showed adequate criterion validity, as its total score was significantly correlated with patients' satisfaction with aesthetics ($rho = 0.30$, $p < 0.001$), chewing function ($rho = 0.47$, $p < 0.001$), and prosthesis ($rho = 0.45$, $p < 0.001$) (Table 3). As for the relationship between the OHIP-14sp total score and the satisfaction-related variables, satisfaction with chewing ($rho = -0.36$), and satisfaction with the prosthesis ($rho = -0.29$) were the only inversely correlated variables at $p < 0.001$. The aesthetic satisfaction variable ($rho = -0.25$) was inversely correlated with the total score of the OHIP-14sp at $p < 0.05$ (Table 3).

As for the construct validity, the factor analysis showed average QoLIP-10 scores ranging from 1.64 for Item 6 to 1.99 for Item 5. Hence, every response was situated in the non-impact zone (Table 2). Both the communalities extracted and the standard deviations obtained for the principal components' analysis support the conclusion that all of the items were well-represented in the factorization. Consequently, all of the items

Table 1 – Impact of the study variables on the OHRQoL (*N* = 84).

Patients' features (%, *n*)	Statistical significance			
	QoLIP-10 total score		OHIP-14sp total score	
	Mean (SD)	*p* values	Mean (SD)	*p* values
Group 1: Social-demographic variables				
Gender				
Male (42.9%, *n* = 36)	18.8 (2.5)	0.15 NS (a)	0.5 (1.6)	0.18 NS (a)
Female (57.1%, *n* = 48)	17.6 (5.7)		1.1 (4.1)	
Age				
≤64 years (42.9%, *n* = 36)	17.6 (5.0)	0.16 NS (a)	0.9 (2.9)	0.43 NS (a)
>65 years (57.1%, *n* = 48)	18.5 (4.6)		0.9 (3.5)	
Marital status				
Single (8.3%, *n* = 7)	14.8 (10.5)	0.09 NS (b)	3.5 (9.0)	0.69 NS (b)
Married (75%, *n* = 63)	18.3 (4.0)		0.8 (2.4)	
Divorced (9.5%, *n* = 8)	20.0 (0.0)		0.0 (0.0)	
Widower (7.1%, *n* = 3)	17.8 (1.9)		0.1 (0.4)	
Level of education/schooling				
Basic education (46.4%, *n* = 39)	17.7 (6.1)	0.27 NS (b)	1.4 (4.5)	0.22 NS (b)
Secodary education (16.7%, *n* = 14)	17.9 (3.1)		0.0 (0.2)	
Special teaching (7.1%, *n* = 6)	16.3 (5.3)		1.3 (3.2)	
University education (29.8%, *n* = 25)	19.3 (1.5)		0.5 (1.3)	
Group 2: Health behavioral variables				
Tooth brushing/daily rate				
Once a day (22.6%, *n* = 19)	19.1 (2.4)	0.20 NS (b)	0.4 (1.2)	0.46 NS (b)
Twice a day (50%, *n* = 42)	17.3 (6.1)		1.4 (4.5)	
Three times a day (23.8%, *n* = 20)	18.6 (2.1)		0.3 (0.9)	
More than three times/day (3.6%, *n* = 3)	20.0 (0.0)		0.0 (0.0)	
Number of dental visits per year				
None (35.7%, *n* = 30)	18.8 (2.2)	0.60 NS (b)	0.9 (1.5)	0.03* (b)
One (52.4%, *n* = 44)	18.2 (4.6)		0.5 (2.6)	
Two (6%, *n* = 5)	13.8 (12.2)		4.8 (10.7)	
More than two (6%, *n* = 5)	18.2 (2.6)		0.0 (0.0)	
Group 3: Self-perceived satisfaction with the mouth, and prosthetic-related data				
Complaints about the mouth				
Yes (13.1%, *n* = 11)	11.7 (9.8)	0.0001** (a)	4.27 (8.0)	0.001** (a)
No (86.9%, *n* = 73)	19.1 (2.1)		0.4 (1.3)	
Perception of the need for dental treatment				
Yes (22.6%, *n* = 19)	16.1 (8.6)	0.80 NS (a)	2.6 (6.3)	0.11 NS (a)
No (77.4%, *n* = 65)	18.75 (2.3)		0.4 (1.3)	
Status of the prosthesis				
Good condition (GC) (59.5%, *n* = 50)	18.0 (4.5)	0.69 NS (b)	0.8 (3.4)	0.98 NS (b)
Needs reparation (R) (19%, *n* = 16)	19.0 (2.5)		0.5 (1.9)	
Requires to be replaced (CH) (21.4%, *n* = 18)	17.6 (6.3)		1.3 (3.8)	
Global oral satisfaction (Visual analogue scale: VAS): Criterion validity of the QoLIP-10				
Aesthetic satisfaction				
Satisfied (70.2%, *n* = 59)	16.6 (0.7)	0.0001** (b)	0.2 (0.7)	0.001** (b)
Neutral (25%, *n* = 21)	16.6 (3.2)		1.1 (2.1)	
Dissatisfied (4.8%, *n* = 4)	2.5 (11.6)		10.0 (12.0)	
Satisfaction with chewing				
Satisfied (72.6%, *n* = 64)	19.7 (0.7)	0.0001** (b)	0.1 (0.7)	0.0001** (b)
Neutral (25%, *n* = 21)	16.1 (3.3)		1.2 (2.1)	
Dissatisfied (2.4%, *n* = 2)	−7.5 (0.7)		20.0 (5.6)	
Satisfaction with the prosthesis/implant restoration				
Satisfied (76.2%, *n* = 64)	19.6 (0.7)	0.0001** (b)	0.1 (0.7)	0.0001** (b)
Neutral (21.4%, *n* = 18)	15.6 (3.4)		1.3 (2.2)	
Dissatisfied (2.4%, *n* = 2)	−7.5 (0.7)		20.0 (5.6)	

Lower QoLIP-10 scores and higher OHIP-14 punctuations indicate poorer self-perceived quality of life. NS = not significant ($p > 0.05$). *Significant at $\alpha = 0.05$. **Significant at $\alpha = 0.001$. (a) Mann–Whitney *U* test. (b) Kruskal–Wallis test.

Table 2 – Factor analysis and reliability of the QoLIP-10 index for fixed implant prosthesis wearers ($N = 84$).

Items' scores			Factor load matrix (factorial weight > 0.5)		
Items (*ordered as in the original version of the index*)	Mean (SD)	Communalities (PCA)	QoLIP-10 dimensions		
			Biopsychosocial	Dental-facial aesthetics	Performance
(1) Oral pain	1.85 (0.7)	0.92	0.85	–	–
(2) Chewing difficulty	1.81 (0.6)	0.84	–	–	0.74
(3) Worry/concern	1.81 (0.7)	0.94	0.86	–	–
(4) Communication/social relations	1.89 (0.6)	0.94	0.87	–	–
(5) Activities of daily living	1.99 (0.1)	0.88	–	–	0.92
(6) Satisfaction with the prosthesis' appearance	1.64 (0.8)	0.94	–	0.75	–
(7) Satisfaction with the realism of the prosthesis	1.68 (0.8)	0.97	–	0.86	–
(8) Satisfaction with the smile	1.71 (0.7)	0.95	–	0.89	–
(9) Speaking difficulty or restriction	1.83 (0.6)	0.87	0.89	–	–
(10) Oral hygiene difficulty	1.95 (0.2)	0.81	–	–	0.74
Percentage of variance explained			35.30%	28.00%	14.58%
Items per dimension in this study (total = 10 items)			4 items (1,3,4,9)	3 items (6,7,8)	3 items (2,5,10)
Dimensional Cronbach α values			0.99	0.98	0.96
Reliability of the QoLIP-10/Cronbach α value of the index = 0.92			Percentage of total accumulated variance = 77.88%		

Low QoLIP-10 scores indicate poor self-perceived quality of life. PCA = principal component analysis.

were necessary in the questionnaire for cement-retained implant prosthesis wearers (Table 2).

Results from the Bartlett's Sphericity test ($\chi^2 = 978.643$, 45gl, $p < 0.00001$) suggested the existence of a high number of inter-significant correlations among items and latent factors (or dimensions) of the QoLIP-10. The KMO measure produced a global value of 0.76. Three components with eigenvalues above 1 emerged from the factor analysis of the QoLIP-10 and were supported by the elbow in the corresponding scree plot of eigenvalues. These three factors explained the 77.88% of the total variance (Table 2). Most items consistently and coherently loaded on a single factor. Table 2 presents the items with factorial weights greater than 0.5 ordered on three dimensions.

The total QoLIP-10 and OHIP-14sp scores were inversely correlated (*rho* = −0.36, $p < 0.001$). The total score of the QoLIP-10 questionnaire did not show significant inverse correlations with the dimensional scores of the OHIP-14sp (Table 3). In turn, the OHIP-14sp total score was inversely correlated ($p < 0.001$) with the *biopsychosocial* and *performance* sub-scale scores of the QoLIP-10 (Table 3). Therefore, subjects registering the highest scores (least impact) in the QoLIP-10 scale tended to present the lowest scores in the OHIP-14sp questionnaire. The identical qualitative interpretation of both tests confirmed the convergent validity of the QoLIP-10 for cement-retained implant prosthesis wearers (Table 3).

To finish with the construct validity, the QoLIP-10 questionnaire satisfactorily proved to be reliable and valid for cemented implant prosthesis wearers because of its psychometric properties (Table 2). This implied that the ten items measured by the index were appropriate.

3.3. *Analysis of the prosthetic well-being construct*

The total scores of the QoLIP-10 and the OHIP-14sp were compared among the four implant prosthodontic groups to evaluate the discriminant validity of the QoLIP-10 index. The QoLIP-10 showed significant differences among the study groups ($p = 0.048$), reporting lower levels of satisfaction among patients wearing cement-retained FDPs supported by 3–5 implants (13.5 ± 10.1). The OHIP-14 scale also pointed to lower levels of satisfaction in the same group (4.7 ± 7.9); however, no statistical significance was achieved (Table 4).

The *performance* dimension of the QoLIP-10 index showed discriminative capacity among the implant prosthodontic groups. Thus, patients wearing cemented FDPs supported by 3–5 implants attained the significantly lowest QoL values in the *performance* domain of the QoLIP-10 ($p = 0.004$) (Table 4). In agreement, the *physical disability* domain of the OHIP-14 registered the significantly worst satisfaction values in the same group ($p = 0.011$).

With regard to the impact of the implant prosthesis on the OHRQoL, the effect of possible modulating factors was also examined. The total score of the QoLIP-10 was significantly lower (indicating lower QoL) in those subjects who complained about their mouths ($p < 0.0001$). Therefore, *complaints about the mouth* acted as a direct modulator or 'predictor' of patients' satisfaction (Table 1). In addition, the *three global oral satisfaction* measures (*i.e.*, satisfaction with the aesthetics, chewing, and prosthesis) (Table 1) were found to influence the QoLIP-10 impact scores in the expected direction ($p < 0.0001$). This corroborates the suitability of the scale for assessing the OHRQoL of cement-retained implant prosthesis wearers and moreover points to its adequate criterion validity. The same factors influencing QoL were consistently detected by the OHIP-14sp (Table 1).

However, the *number of dental visits per year* was identified as a direct modulator of patients' satisfaction ($p = 0.03$) only by the OHIP-14sp. Social-demographic variables (Group 1), frequency of tooth-brushings (Group 2), perception of the

Table 3 – Correlation among satisfaction variables and QoLIP-10 and OHIP-14sp scores (*N* = 84).

			rho values	
			QoLIP–10 total score	**OHIP–14sp total score**
Variables				
Aesthetic satisfaction			0.30 **	- 0.25 *
Satisfaction with chewing			0.47 **	- 0.36 **
Satisfaction with the prosthesis			0.45 **	- 0.29 **
Questionnaires				
QoLIP–10	**Sub-scale and total scores**	***Biopsychosocial***	0.66 **	- 0.37 **
		Dental-facial aesthetics	0.88 **	- 0.14 NS
		Performance	0.76 **	- 0.45 **
		QoLIP–10 total score	N/A	- 0.36 **
OHIP–14sp		***Functional limitation***	- 0.16 NS	0.77 **
		Pain	- 0.18 NS	0.80 **
		Psychological discomfort	- 0.18 NS	0.78 **
		Physical disability	- 0.00 NS	0.46 **
		Psychological disability	- 0.11 NS	0.39 **
		Social disability	N/A	N/A
		Handicap	N/A	N/A
		OHIP–14sp total score	**Convergent validity of the QoLIP–10:** - 0.36 **	N/A

NS = not significant ($p > 0.05$). (*): significant at $\alpha = 0.05$. (**): significant at $\alpha = 0.001$. *rho:* Spearman's rank correlation coefficients. N/A = not applicable.

NS = not significant ($p > 0.05$). *Significant at $\alpha = 0.05$. **Significant at $\alpha = 0.001$. *rho:* Spearman's rank correlation coefficients. N/A = not applicable.

Table 4 – Comparison of self-reported satisfaction among the fixed implant prosthetic groups tested.

Subscale and total scores	Screwed denture wearers 2 implants ($n = 35$)	Screwed denture wearers 3–5 implants ($n = 7$)	Cemented denture wearers 2 implants ($n = 36$)	Cemented denture wearers 3–5 implants ($n = 6$)	p values (Kruskal–Wallis) ($N = 84$) Discriminant validity
	Mean (SD)				
QoLIP-10					
Biopsychosocial	7.8 (0.7)	6.2 (4.5)	7.8 (0.6)	5.8 (4.4)	0.33 NS
Dental-facial aesthetics	5.0 (1.7)	3.0 (5.1)	5.6 (0.9)	3.5 (3.8)	0.55 NS
Performance	5.8 (0.6)	5.43 (1.5)	5.6 (0.7)	4.1 (2.2)	0.004*
QoLIP-10 total score	18.7 (2.5)	14.7 (10.5)	19.0 (2.0)	13.5 (10.1)	0.048*
OHIP-14sp					
Functional limitation	0.1 (0.4)	1.1 (3.0)	0.1 (0.3)	0.5 (0.8)	0.26 NS
Pain	0.2 (0.4)	0.0 (0.0)	0.3 (0.9)	1.3 (2.8)	0.38 NS
Psychological discomfort	0.0 (0.2)	1.1 (3.0)	0.3 (0.7)	1.6 (3.2)	0.32 NS
Physical disability	0.0 (0.0)	1.1 (3.0)	0.0 (0.0)	0.3 (0.8)	0.011*
Psychological disability	0.0 (0.0)	0.0 (0.0)	0.1 (0.6)	0.3 (0.8)	0.10 NS
Social disability	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	1.00 NS
Handicap	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	1.00 NS
OHIP-14sp total score	0.4 (0.9)	3.4 (9.0)	0.8 (2.2)	4.7 (7.9)	NS

NS = not significant ($p > 0.05$). *Significant at $\alpha = 0.05$.

need for dental treatment, and status of the prosthesis (Group 3), did not affect patient satisfaction (Table 1).

4. Discussion

Notwithstanding the progressive development of more predictable implant prosthetic rehabilitations,[32] the use of patient-centred outcome measurement techniques may be helpful in facilitating a more appropriate patient-oriented solution.[33,34] In this study, the QoLIP-10 scale has been validated for cement-retained implant-supported prosthesis wearers. The impact of cemented and screwed restorations on patient satisfaction was also evaluated on the basis of cross-sectional survey-based data and clinical examination.

The results require rejection of the null hypotheses because: (1) the type of fixed implant restoration influenced the level of patient satisfaction; and (2) various study variables modulated the OHRQoL of cemented and screwed implant-supported prosthesis wearers. One limitation of the study was that the participants were recruited from a single university dental clinic. Moreover, the presence of uncontrolled confounding factors that are inherent in clinical trials might have affected the results to some extent.[35] Nonetheless, the heterogeneity of the sample (Table 1) may allow the extrapolation of the findings to other populations.[4,21,25]

Taking into account that those subjects who participated in the pilot trial understood the entire questionnaire, and that the instrument did not lack any important content, the face and content validities of the QoLIP-10 were confirmed.[17,31,36]

The high Cronbach's alpha value[27] corroborated the reliability of the QoLIP-10 scale in the main study (Table 2). A strong correlation between the total and dimensional QoLIP-10 scores revealed internal consistency[18,27] (Table 3). Besides, the ten items of the index surpassed a threshold of 0.2 in the item-total correlation matrix, which is the basic condition for including an item on a scale.[18] The bidirectional measurement of responses of the QoLIP-10 is more complete than the exclusive evaluation of negative effects made by the OHIP-14 (among others).[31,37] This is crucial, as most of the QoLIP-10 items are rated as positive events in this research.

According to previous investigations,[5,28,31] the criterion validity of the QoLIP-10 was proven by the fact that its total score was positively correlated with all of the satisfaction variables (Tables 1 and 3). Those patients who reacted positively to the aesthetic results and comfort with eating, and were overall satisfied with their implant restorations,[38] registered significantly higher QoLIP-10 scores, meaning a higher QoL (Table 1). The results presented here are in agreement with those of previous research on implant prosthesis wearers that used the QoLIP-10 index.[5,6] In a retrospective study,[39] a positive response of the patients was obtained for the variable *aesthetics and satisfaction* in case of single-tooth implant restorations. In another study in which a 13-question visual analog scale (VAS) was applied, most patients (>90%) were completely satisfied with their chewing function and aesthetics.[40] Unfortunately, disparities in study protocols (*i.e.*, number of implants, design of the prostheses, type of questionnaires used, variables registered, etc.) make comparisons difficult.

Relating to the construct validity, the multidimensionality of the QoLIP-10 was evidenced by the exploratory factor analysis, which displayed three statistically differentiated emerging dimensions (Table 2). According to previous related studies,[5,6,30,41] a simple structure was obtained because each item was weighted heavily and solely on one dimension

(Table 2). The convergent validity of the QoLIP-10 was supported by: (a) the logical inverse convergence (*rho* = −0.36, $p < 0.001$) between the total scores of the QoLIP-10 and OHIP-14sp;[5,6,18,29,31] and (b) significant inverse correlations among the total score of each questionnaire and some sub-scale scores of the other test (Table 3). These associations confirmed that the QoLIP-10 questionnaire assessed the same construct.[18] This is relevant, since the OHIP-14sp had recently been validated in the same reference population.[10]

As for the discriminant validity, the *performance* dimension of the QoLIP-10 significantly discriminated among the tested groups (Table 4). This index attributed the worst self-perceived satisfaction to cement-retained implant prostheses supported by 3–5 implants, with significant differences with the other groups. The *physical disability* domain of the OHIP-14 questionnaire showed the same results (Table 4). Thus, both the extension and the type of retention of the implant prostheses may influence the patient self-perceived QoL (Table 4). Several authors[42–44] reported reduced discriminatory capacity with implant-supported restorations with respect to natural teeth due to the absence of a periodontal ligament (PDL)[45,46] which is considered essential for oral tactile function.[47] In agreement, Chaar et al.[11] recommended treating long-span and full-arch fixed dental prostheses (FDPs) with screw-retained solutions. Given that a further extension of the rehabilitation increases the likelihood of complications, the retrievability of screwed FDPs may be less traumatic and more predictable in such cases, when compared to cemented systems.[11]

Contrary to previous studies that used the QoLIP-10 questionnaire,[6] the prosthodontic groups were discriminated by the total score of this scale (Table 4). The best QoL was associated with implant cemented prostheses supported by two implants. The lack of screw holes in cemented prostheses provides a design that enhances the physical strength of porcelain, resulting in lower fracture rates.[12,14] However, the contacts made in the occlusal composite that covers the screw holes are unstable in the long-term.[15] The loss of composite may result in more visits to the dentist and increased maintenance that adversely impacts the patients' well-being. Also, the screw holes in the occlusal surfaces provide poor esthetics and cannot meet the expectations of patients, even in the case of short restorations.[12]

Although no significant differences were identified with regard to the socio-demographic variables, the profile of the subjects reporting the highest psychological discomfort was a single woman having a basic or special education, which was consistently detected by both questionnaires (Table 1). Psychological differences between men and women would help explain the possible effect of *gender* on patient satisfaction, as the perception of individuals is more strongly influenced by self-evaluation than by objective parameters.[48] Patients with higher educational level showed higher satisfaction with respect to those having basic education (Table 1). Such tendency was announced by Preciado et al.,[6] in case of wearers of screwed implant restorations. Age was not a modulating factor of well-being (Table 1); which is consistent with a study on conventional complete denture wearers conducted in the same reference population.[25] As in previous research,[6,25] single patients tended to express poorer overall satisfaction than those who were married. This finding should be further analysed.

No significant differences were found when the scores of the QoLIP-10 scale were crossed with the health behavioral variables (Table 1). Nonetheless, a better QoL was associated with more frequent tooth brushings, which emphasizes the importance of teaching patients to practice healthy habits.[29] Logically, patients who *complained about their mouths* reported a significantly lower QoL, which agrees with the literature[4,21,25] (Table 1).

The psychometric capacity of the QoLIP-10 index for estimating the effect of cemented implant prostheses on patients' well-being may be relevant for decision-making, measuring clinical outcomes, and research purposes. In our investigation, patient satisfaction depended upon the extension and the type of retention of fixed implant restorations, which is in agreement with previous research.[49,50] Particularly, when compared to screwed FDPs, short cemented implant restorations lead to greater improvements in patients' self-perceived QoL.

5. Conclusions

Within the limitations of this study, the following conclusions may be drawn:

1. The QoLIP-10 is a valid and reliable index for estimating the level of satisfaction of future patients wearing cement-retained implant-supported prostheses.
2. The extension and the type of retention of the restoration may compromise the patients' satisfaction. The highest QoL was associated with short implant cemented partial prostheses supported by two implants, as shown by the QoLIP-10 scale.
3. The *performance* dimension of the QoLIP-10 significantly discriminated among the tested groups; attributing the worst self-perceived satisfaction to long-span cemented restorations supported by 3–5 implants.
4. The variable *complaints about the mouth* and the *three global oral satisfaction measures* were direct modulators of patient satisfaction.

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6.2. ARTÍCULO II: Carmen Perea, Jaime Del Río, Arelis Preciado, Christopher D. Lynch, Alicia Celemín, Raquel Castillo-Oyagüe. **Validation of the 'Quality of Life Implant Prostheses (QoLIP-10)' questionnaire for wearers of cement-retained implant-supported restorations.** Journal of Dentistry 2015; 43: 1021-31.

(Validación del cuestionario 'Calidad de Vida con Implantoprótesis (QoLIP-10)' para portadores de restauraciones implantosoportadas cementadas).

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TRADUCCIÓN DEL RESUMEN

Objetivos: *Validar el cuestionario "Calidad de Vida con Implantoprótesis" ('QoLIP-10') para evaluar el impacto de las prótesis cementadas sobre implantes en la calidad de vida asociada a la salud oral (OHRQoL).* ***Métodos:*** *84 sujetos portadores de restauraciones implantológicas fueron distribuidos de la siguiente forma: Grupo 1 (SD-I; n = 35): prótesis fijas atornilladas sobre 2 implantes; Grupo 2 (SD-II; n = 7): prótesis fijas atornilladas sobre 3-5 implantes; Grupo 3 (CD-I; n = 36): prótesis fijas cementadas sobre 2 implantes; y Grupo 4 (CD-II; n = 6): prótesis fijas cementadas sobre 3-5 implantes. Se utilizaron el QoLIP-10 (Anexo 10.5) y el OHIP-14sp (Anexo 10.3). Se recogieron los datos referentes a la satisfacción oral global, datos socio-demográficos, de salud y relativos a la prótesis. Se investigó la fiabilidad y la validez del QoLIP-10. Las correlaciones entre ambos índices fueron exploradas mediante el test de Spearman. Se calculó la estadística descriptiva y se aplicaron tests no paramétricos para evaluar el efecto de las variables de estudio en la calidad de vida asociada a la salud oral (OHRQoL) (α = 0,05).* ***Resultados:*** *EL QoLIP-10 confirmó su capacidad psicométrica para usuarios de prótesis cementadas sobre implantes. Los dos tests empleados mostraron una correlación inversa entre sí. El QoLIP-10 atribuyó la calidad de vida (QoL) significativamente peor a las prótesis cementadas de mayor longitud. Los grupos fueron discriminados significativamente por la dimensión de "Rendimiento funcional". La variable* Quejas respecto a la boca *y las tres medidas de satisfacción oral global modularon significativamente la OHRQoL.* ***Conclusiones:*** *La satisfacción del paciente depende de la*

extensión y el tipo de retención de las prótesis fijas sobre implantes. ***Significación clínica:*** *El QoLIP-10 puede ayudar a estimar el efecto de las prótesis fijas cementadas sobre implantes en el bienestar de los pacientes. En comparación con las atornilladas, las restauraciones cementadas cortas conducen a una autopercepción más positiva de calidad de vida por parte del paciente.*

Title: Validation of the 'Quality of Life Implant Prostheses (QoLIP-10)' questionnaire for wearers of cement-retained implant-supported restorations.

Short title: Validation of the QoLIP-10 in cemented implant-prosthesis' wearers.

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Key words: Quality of Life with Implant-Prostheses (QoLIP–10); Oral Health Impact Profile (OHIP); Oral health-related quality of life (OHRQoL); patient satisfaction; cemented implant-supported prosthesis; screwed implant-supported prosthesis.

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Oral aesthetic-related quality of life of muco-supported prosthesis and implant-retained overdenture wearers assessed by a new, short, specific scale (QoLDAS-9)

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ABSTRACT

Objectives: To validate a new questionnaire for evaluating the 'Oral aesthetic-related quality of life (OARQoL)' of prosthetically restored patients. 'OARQoL' assesses the impact of the self-perceived dental aesthetics on patients' well-being.
Methods: The 'Quality of Life associated with Dental Aesthetic Satisfaction (QoLDAS)' index was designed. After a pilot trial, 70 patients were distributed into two groups depending on their type of prosthetic rehabilitation: Group 1 (CD; $n=34$): muco-supported complete dentures, and Group 2 (IO; $n=36$): implant-retained overdentures. Patients answered the QoLDAS and the Oral Health Impact Profile (OHIP-20sp) questionnaires, and reported their satisfaction on a visual analogue scale (VAS). Socio-demographic and prosthesis-related factors were registered. Psychometric properties of the QoLDAS were investigated. Correlations between both indices were explored using the Spearman's rank test. Descriptive and non-parametric probes were run to evaluate the effect of the study variables on the OARQoL ($\alpha=0.05$).
Results: The QoLDAS-9 was reliable and valid. The factor analysis confirmed the existence of three dimensions and meaningful inter-correlations among the nine finally included items. Both scales were inversely correlated. The self-reported aesthetic and functional satisfaction and the education level significantly modulated the OARQoL as measured with the QoLDAS-9.
Conclusions: The QoLDAS-9 confirmed its psychometric capacity for assessing the OARQoL of CD and IO wearers. Both groups showed comparably high OARQoL. Superior education degrees lead to lower OARQoL.
Clinical significance: The QoLDAS-9 may be recommended for anticipating the effect of prosthetic restorations on OARQoL. CD and IO are predictable treatment options for improving the aesthetic self-perception of edentulous patients.

1. Introduction

'Clinical success' in prosthetic dentistry has traditionally been described as a combination of 'function', 'comfort', and 'aesthetics' [1–5]. As this conceptual triad influences the acceptance and preferences in treatment [6], it would be convenient to discriminate the impact of these aspects on the oral health-related quality of life (OHRQoL) of edentulous patients.

The effect of 'function' and 'comfort' of total rehabilitations on OHRQoL may be objectified, among others, with the Oral Health Impact Profile (OHIP), which is the most widely used instrument in case of edentulism [7–12]. The recently-introduced Quality of Life with Implant-Prostheses (QoLIP-10) questionnaire has been demonstrated to be specifically reliable and valid for dental implant restorations [9,13,14]. However, the generic OHIP scale allows comparing the results more easily when a group of conventional complete denture wearers is included in the study [6,12,15,16]. This index may then prove the removable prostheses' effectiveness taking into account the patients' subjectivity when they express their feelings [8].

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With respect to the third factor, edentate patients associate their 'aesthetics' with not only the way the denture looks in the mouth, but also with their perioral condition and overall facial attractiveness [17–21]. Hence, those restorations that improve the dental and facial appearance could result in a clearly positive effect on patients' self-esteem, socialization, and satisfaction [19].

Given the growing demand for aesthetics in restorative dentistry, the authors suggest the term: 'Oral aesthetic-related quality of life (OARQoL)' (which is comprised within the complex and multidimensional concept of OHRQoL), to focus on the impact of the self-perceived dental aesthetics on the patients' well-being.

To date, the only existing questionnaire that evaluates the satisfaction with dental aesthetics (OHIP-aesthetic) [15] is not applicable to rehabilitated edentulous subjects, but mainly to dentate patients. Therefore, this study aims to develop and validate a specific, short, and effective index for assessing the OARQoL of prosthetically restored edentate patients. The information achieved may help predict the aesthetic self-perception and satisfaction of edentulous patients on the basis of their peculiarities, expectations, socio-demographic profile, and other prosthesis-related features.

While implant-retained overdentures seem to offer improved function and comfort compared with muco-supported prostheses [7–9], the latter allow avoiding surgical risks and other difficulties and costs that are inherent in implant therapy [22]. In this respect, it would be interesting to know whether the aesthetic self-perception supplied by a complete denture could somewhat compensate for other associated drawbacks.

In addition to the design and validation of the new questionnaire, two null hypotheses were tested: (1) both types of prostheses (conventional dentures and implant-retained overdentures) provide comparable levels of OARQoL; and (2) the OARQoL does not depend on socio-demographic and/or prosthesis-related variables.

2. Material and methods

2.1. Development of the 'Quality of Life associated with Dental Aesthetic Satisfaction' (QoLDAS) questionnaire

Following the EUROHIS [23] guidelines for the development of a universal instrument related to quality of life (QoL), a comprehensive review of the scientific literature [1,9–13,16,24] was completed to establish a theoretical framework and consensus about the content and preliminary structure of the questionnaire.

A team of five specialists in prosthodontics and an oral and maxillofacial surgeon (each with demonstrated research experience in QoL), selected the most relevant items in OARQoL for consideration in wearers of conventional complete dentures and implant-retained overdentures. The development of the new scale was thus supported by previously published articles and based on existing questionnaires in the areas of self-image/aesthetics, self-esteem, and socialization [9,25].

The research group interviewed 40 patients who were rehabilitated at the Faculty of Dentistry of the Complutense University of Madrid (UCM, Spain) [9]. Participants attended an in-depth, face-to-face interview, and were distributed in group discussions (focus discussions). The purpose was to identify what they regarded as most important aesthetic requirements related to OARQoL. The experts selected and summarised the most prevalent issues. At this stage, redundant or inappropriate items were deleted [9,23,24].

Finally, the committee of experts designated the 'Quality of Life associated with Dental Aesthetic Satisfaction' scale, hereafter called 'QoLDAS', which was initially composed of the following items: appropriate teeth size, appropriate length of the teeth during laughing, appropriate teeth colour, appropriate teeth position, would not change the prosthetic teeth, improving the facial profile, improving the lip support, feeling younger, feeling more self-confident, having received congratulations because of the prosthetic rehabilitation, and improving the social relations. The questionnaire may be easily adapted to a global scale format to be applied in future evaluations. Thus, patients could be asked: *'Do you think that the following aspects related to appearance have improved, worsened, or remained the same after the prosthetic treatment?'*[26].

The QoLDAS was developed to be intuitively self-completed as the items' responses were expressed in a Likert-type scale [27] with proportional codes for the impact degrees. The items evaluated as '<0' on the Likert scale were considered as having negative impact, while values of '+1' and '+2' represented the positive side of each item (absence of negative effect). The possible responses are: 'strongly disagree' (score −2), 'disagree' (score −1), 'indecisive'/'indifferent'/'neutral' (score 0), 'agree' (score +1), and 'strongly agree' (score +2). The QoLDAS total score is the sum of the different item scores [28], and ranges between '$-2 \times$ no. of items' and '$+2 \times$ no. of items'. Hence, both negative and positive impacts contributed to the total score in such way that the higher the total score, the higher the satisfaction of the patient (meaning that negative or low positive scores indicate poorer self-perceived OARQoL).

Following the recommendations of Streiner and Norman [26] the face and content validity of the QoLDAS was empirically checked in a pilot trial conducted on a representative sample of patients ($n = 22$) from the same source population, which constituted about 22.4% of the main study sample ($n = 98$) (however, the patients of the pilot trial were different from the patients making up the main study sample). Although ten (or even fewer) patients have proven to be sufficient to assess the clarity of instructions, item wording, acceptability of formatting, and ease of administration of a questionnaire [29]; given the population variability in this study [26,29] 11 patients per treatment group were selected for the pilot trial. Thus, they wore complete dentures and implant-retained overdentures and met selection criteria that were similar to those of the patients in the main investigation. The comprehensiveness of the QoLDAS index was evaluated by asking the volunteers specific questions about possible difficulties in understanding the items in order to improve the intelligibility of the instrument and to optimize its face and content validity for the main cross-sectional investigation [24,26,29].

2.2. Study protocol

2.2.1. Study sample

The reference population included 98 subjects aged from 50 to 92 years, who were treated with conventional complete dentures or implant-retained overdentures at the Department of Buccofacial Prostheses of the Complutense University of Madrid (UCM, Spain) between 2005 and 2013.

The subjects were invited to take part in this cross-sectional study when they attended the clinic for a routine review between December of 2014 and February of 2015. The exclusion criteria were: patients wearing both an implant-retained overdenture and a complete denture (to avoid misinterpretation of the findings), patients seeking dental treatment, and patients with cognitive impairment, motility disorders, implant loss, and/or serious illness [8,9].

The 70 final volunteers were scheduled for appointments that were to take place in March of 2015. These subjects were divided into two groups depending on their type of prosthetic rehabilitation: Group 1 (CD; $n = 34$): conventional complete dentures, and Group 2 (IO; $n = 36$): implant-retained overdentures.

The study was conducted following the ethical principles of medical investigation involving human subjects under the Helsinki Declaration of the World Medical Association (http://www.wma.net) and the Spanish Law 14/2007 of July 3rd for Biomedical Research (http://www.boe.es). All of the participants were briefed about the purpose and process of the study. The Ethics Committee Approval (C.E.I.C., San Carlos University Hospital, Madrid; C.I. 12/240-E and 12/241-E) and the patients' approved written consent were obtained. Confidentiality was preserved.

2.2.2. Data gathering

The participants completed the QoLDAS questionnaire aided by a trained interviewer who formulated the questions [30]. Patients also completed the OHIP-20sp questionnaire, which had been previously validated in the Spanish population [10]. Answering the OHIP-20sp, subjects scored in terms of frequency the presence of 20 situations of impact that were conceptually divided into seven 'dimensions' or 'domains' (i.e., functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap). Frequency was codified using a classic Likert-type Scheme [27] with five options [8,31]. The possible impact responses were: 'hardly ever' (score +1), 'occasionally' (score +2), 'fairly often' (score +3), and 'very often' (score +4). The 'never' response (score 0) revealed the absence of impact. The OHIP-20sp outcome variable ranged from 0 to +80. With this index, the higher the total score is, the higher the level of negative impact on oral well-being and quality of life is, and, therefore, the lower the satisfaction of the patient is [10].

The volunteers were also asked about their overall satisfaction with their mouths, which comprised individual assessments of the satisfaction with their oral aesthetics, functionality, and comfort with their prostheses [13,14,32]. A visual analogue scale (VAS) was used for each of the abovementioned areas, so that these perceptions were quantified in a continuous range from 0 to 10 [13,33]. Subjects could thereby declare themselves to be 'dissatisfied', 'neutral', or 'satisfied', offering values situated left to the midpoint of a 100-mm long line, on the midpoint, or to the right of the midpoint, respectively [9,13,14,33].

After the patients' evaluation, the interviewer also used a VAS scale to determine an objective rating of the aesthetic appearance of the rehabilitations. The dentist used the following criteria to score as 'dissatisfied': (a) existence of problems related to the prosthesis design (deviated midline; irregular gingival contour; incorrect colour, size, and/or position of the prosthetic teeth; insufficient or excessive lip support; and/or excessive prosthetic gingival display); (b) existence of problems related to the use and maintenance of the denture (wear, fractures, calculus, and/or stains); and (c) combinations among both types of problems.

A different investigator conducted each questionnaire. To ensure that the clinic staff had no access to the patients' responses, the completed forms were placed in sealed envelopes. The QoLDAS, the OHIP-20sp, and the VAS evaluations were then linked by means of a unique identification code for each participant [9,32].

To capture the clinical modulating factors, subjects were examined by a single researcher using the diagnostic methodology published by the World Health Organization (WHO) [8,13,14,34]. The study variables were distributed as follows: Group 1 of variables: Socio-demographic factors (gender, age, marital status, and level of education); and Group 2 of variables: Factors related to the prosthesis and its maintenance (location of the prosthesis, date of installation, and number of dental visits per year).

2.3. Data analysis

The additive method (–ADD) [10,16,33] was used for both the QoLDAS and the OHIP-20sp analyses by adding the item codes at the appropriate frequency [8,28]. The dimensional scores of each index were obtained in a similar fashion. All of the data collected were processed according to well-established statistical methods used in related research [8,9,13,14].

Descriptive statistics and percentages for qualitative and categorical variables were calculated [8,9,13,14].

The main psychometric characteristics of the QoLDAS questionnaire (reliability and validity) were investigated. On the one hand, as each item measured different aspects of the same attribute, the reliability was assessed by examining the internal consistency of the scales through the use of the Cronbach's α value, the α value if an item was deleted, the inter-item correlation, and the item-total correlation [35,36]. On the other hand, different types of validity were tested:

(a) The face and content validity (which refers to the extent to which a measure represents all facets of a given construct) were verified in the pilot trial because the patients reported no difficulties in understanding the items and did not mention any situation of impact that had not been included in the questionnaire [10].
(b) The construct validity of the QoLDAS (or the extent to which the OARQoL was actually recorded with this scale) [10,36] was examined using the factor analysis (a data reduction technique that allows homogeneous subgroups of variables to be found), and the convergent validity of the scale (which measures how closely the new questionnaire is related to other variables and measures of the same construct to which it should be related) [26].
Concerning the factor analysis, the principal components' analysis (PCA) was performed along with the rotation method: the Varimax plus Kaiser normalization was chosen to extract the underlying dimensions of the 'satisfaction with dental appearance' construct [9,37]. Then, the Bartlett's Sphericity and the Kaiser–Meyer–Olkin (KMO) tests, which are measures of sampling adequacy, were run to detect the factorial structure of the QoLDAS [9,32]. Factors with an eigenvalue of less than one were disregarded to avoid distortion [13,14,32]. The items were assigned to the rotated factors (or dimensions) when they had a loading of 0.5 or greater in a single factor [9,13,14,24].
To establish the degree of convergent validity, the QoLDAS total and sub-scale scores were correlated to the total score of the OHIP-20sp using the Spearman's rank test [24].
(c) The criterion validity of the QoLDAS indicator (which measures how well the test predicts the OARQoL based on information obtained from other variables) [10,36] was analysed by contrasting the total QoLDAS and OHIP-20sp scores with the VAS punctuations using non-parametric probes, since the Kolmogorov–Smirnov test did not assume a normal distribution of the QoLDAS outcome variable in the prosthodontic groups. The Kruskal–Wallis test was applied for variables with three or more categories, and the Mann–Whitney U test was run for variables with two categories [9,13,14,25,38].
(d) To investigate the discriminant validity, the total and dimensional scores of the QoLDAS were compared with the total score of the OHIP-20sp among the prosthodontic groups using the Mann–Whitney U test [9,10,13,14].

After evaluating the psychometric properties of the new index, the influence of possible modulating factors on the impact scores of the QoLDAS were explored with the Kruskal–Wallis and the Mann-Whitney U tests [13,38].

Data were processed using the Statistical Package for the Social Sciences (software v.22) (SPSS/PC+, Inc.; Chicago, IL, USA) taking in

advance the cut-off level for statistical significance at $\alpha = 0.05$ [7–9,37,38].

3. Results

3.1. Description of the sample

A total of 28 patients (28.57%) were excluded from the reference population ($n = 98$). Twelve of them could not be contacted because of changes in their phone number. Six of them could not participate in the study due to medical reasons or death. The remaining ten patients refused to participate due to time constraints (rejection rate: 10.2%). The final study sample was composed of 70 individuals.

From a socio-demographic point of view (Group 1 of variables), the main profile was that of a patient (50% women, 50% men), aged from 50 to 75 years (52.9%), married (61.4%; $p < 0.001$), with a basic education (71.4%; $p < 0.001$) (Table 1).

Concerning the factors related to the prosthesis and its maintenance (Group 2 of variables), the predominant location was 'bimaxillary' for both CD (32.8%) and IO (31.4%), most of the restorations had been in function for 5 years or less (64.3%), and 71.4% of the study subjects did not visit the dentist every year ($p < 0.001$) (Table 1).

With regard to the VAS analysis, most participants were 'satisfied' with their aesthetics (97.1%, $n = 68$; $p < 0.001$), function (87.1%, $n = 61$; $p < 0.001$), and comfort (90%, $n = 63$; $p < 0.001$). Results of the aesthetic evaluation made by the dentist did not significantly differ from the outcomes obtained by the patients ($p = 0.56$). Thus, the practitioner was 'satisfied' with 85.7% ($n = 60$) of the prostheses ($p < 0.001$) (Table 2) and felt 'dissatisfied' with the remaining 14.3% ($n = 10$). Among them, 1.4% ($n = 1$) of the restorations had design-related drawbacks, 10% ($n = 7$) had problems derived from the use and maintenance of the denture, and 2.9% ($n = 2$) showed a combination of both preceding factors.

3.2. Analysis of the reliability and validity of the QoLDAS index

The reliability (or internal consistency) of the QoLDAS instrument was supported by Chronbach α values of 0.78 (direct values)

Table 1
Features of the participants ($N = 70$).

Study variables	Descriptive statistics		QoLDAS-9 total score: crossing variables	
	% (n)	p-value (Chi^2 test)	Mean (SD)	p-value
Group 1 of variables: socio-demographic factors				
Gender				
Male	50% (35)	1.000 NS	11.7 (8.7)	0.14 NS[a]
Female	50% (35)		12.8 (5.0)	
Age				
50–75 years	52.9% (37)	0.72 NS	13.0 (7.7)	0.76 NS[a]
>75 years	47.1% (33)		11.4 (6.2)	
Marital status				
Single	5.7% (4)	0.00**	13 (4.2)	0.96 NS[b]
Married	61.4% (43)		12.5 (7.8)	
Divorced	2.9% (2)		13.5 (6.3)	
Widower	30% (21)		11.5 (6.3)	
Level of education / schooling				
Basic education (BE)	71.4% (50)	0.00**	13.7 (7.2)	0.02*,b
Secondary education (SE)	8.6% (6)		6.3 (3.8)	Aesthetic satisfaction:
Special teaching (ST)	7.1% (5)		13.6 (3.3)	BE/ST > SE/UE
University education (UE)	12.9% (9)		7.4 (5.4)	
Group 2 of variables: factors related to the prosthesis and its maintenance				
Location of the prosthesis				
Complete dentures (CD, $n = 34$)				
Maxillary	15.7% (11)	0.00**	19.6 (9.2)	0.9 NS[a]
Mandibular	–		–	
Bimaxillary	32.9% (23)		19.4 (8.2)	
Implant overdentures (IO, $n = 36$)				
Maxillary	7.1% (5)	0.00**	21.4 (6.3)	0.8 NS[a]
Mandibular	12.9% (9)		19.4 (9.2)	
Bimaxillary	31.4% (22)		22.8 (16.0)	
Date of installation of the prosthesis				
≤5 years	64.3% (45)	0.07 NS	13 (7.8)	0.91 NS[a]
>5 years	35.7% (25)		10.9 (5.4)	
Number of dental visits per year				
None	71.4% (50)	0.00**	12.1 (5.5)	0.12 NS[b]
One	21.5% (15)		11.8 (11.5)	
Two or more	7.1% (5)		14.6 (4.2)	

Higher scores indicate major satisfaction with aesthetics. NS, not significant ($p > 0.05$).
* Significant at $\alpha = 0.05$.
** Significant at $\alpha = 0.001$.
[a] Mann–Whitney U test.
[b] Kruskal–Wallis test.

Table 2
Criterion validity of the QoLDAS-9 index: comparison with the VAS results.

Patients' satisfaction ($N = 70$)	% (n)		p-value (Chi^2 test)	VAS scores Questionnaires: crossing variables	
			Mean (SD)	QoLDAS-9	OHIP-20sp
Aesthetic satisfaction (Dentist)					
Satisfied	85.7% (60)	0.00**	12.4 (7.2)	0.86 NS[a]	0.42 NS[a]
Neutral	0% (0)		–		
Dissatisfied	14.3% (10)		11.4 (6.6)		
Aesthetic satisfaction (Patient)					
Satisfied	97.1% (68)	0.00**	20.3 (6.8)	0.16*,a	0.16*,a
Neutral	2.9% (2)		0.0 (0.0)		
Dissatisfied	0% (0)		–		
Function satisfaction (Patient)					
Satisfied	87.1% (61)	0.00**	13.1 (6.7)	0.12*,a	0.04*,a
Neutral	11.5% (8)		5.5 (6.5)		
Dissatisfied	1.4 (1)		16 (–)		
Comfort satisfaction (Patient)					
Satisfied	90% (63)	0.00**	12.7 (6.9)	0.80 NS[a]	0.03*,a
Neutral	8.6% (6)		6.3 (7.3)		
Dissatisfied	1.4% (1)		16 (–)		

Higher scores indicate major satisfaction with aesthetics. NS, not significant ($p > 0.05$); VAS, visual analogue scale; QoL, quality of life.
* Significant at $\alpha = 0.05$.
** Significant at $\alpha = 0.001$.
[a] Kruskal–Wallis test.

Table 3
Factor analysis and reliability of the QoLDAS-9 questionnaire ($N = 70$).

Items' scores			Factor load matrix (factorial weight >0.5)		
Items	Mean (SD)	Communalities (PCA)	QoLDAS-9 dimensions		
			Psycho-facial aesthetic	Interactive aesthetic	Socio-dental aesthetic
(1) Appropriate teeth size	1.60 (0.91)	0.82	–	–	0.62
(2) Appropriate length of the teeth during laughing	1.69 (0.81)	0.65	–	–	0.70
(3) Would not change the teeth	1.69 (0.97)	0.94	–	0.53	–
(4) Improving the facial profile	1.17 (0.95)	0.90	0.88	–	–
(5) Improving the lip support	1.21 (1.02)	1.04	0.86	–	–
(6) Feeling younger	1.17 (1.72)	2.96	–	0.93	–
(7) Feeling more self-confident	1.34 (0.88)	0.78	0.59	–	–
(8) Having received congratulations because of the rehabilitation	1.01 (1.08)	1.17	–	–	0.82
(9) Improving the social relations	1.40 (2.46)	6.04	–	0.94	–
*Appropriate teeth colour	1.76 (0.65)	0.42	–	–	–
*Appropriate teeth position	1.84 (0.47)	0.22	–	–	–
Percentage of variance explained	N/A	N/A	24.8%	23.6%	23.5%
Cronbach α value	N/A	N/A	0. 78	0. 78	0.76
Items included per dimension (total = 9 items)	3 items (4, 5,7)	3 items (3, 6, 9)	3 items (1, 2, 8)		

Reliability of the QoLDAS- 9 scale / Cronbach α value = 0.83.
Percentage of total accumulated variance = 71.9%.
Higher scores indicate major satisfaction with aesthetics; N/A, not applicable; PCA, principal component analysis.
*Items excluded from the final version of the index as a result of the factor analysis.

and 0.83 (typical values) (Table 3). These results were significant ($p < 0.0001$); therefore, the reliability of the index was estimated to be within the interval of 0.34–0.67 with a 95% degree of confidence. Alpha values were lower or equal when either item was deleted.

The inter-item correlation analysis displayed an overall distribution of positive items (ranging from 0.14 between Items 6 and 8, to 0.84 between Items 6 and 9). This fact revealed that the concept was measured in the same direction. Although most correlations were significant, none of them was intense enough to verify the existence of clear redundancy in content. In the item-total correlation matrix, two items (i.e., 'teeth position' and 'teeth colour') did not surpass the threshold of 0.20, which is the minimum requirement for including an item on a scale [26]. Thereby, the nine items that were finally included in the test exhibited adequate homogeneity with coefficients ranging from 0.45 to 0.67. As the items and their possible responses were presented together in a matrix (which facilitates self-completion by patients), the face and content validity of the index was considered adequate in the pilot trial. The participants did not

mention any situation of impact that was not included in the questionnaire and declared that all of the items were comprehensible. Additionally, the symmetric format of the Likert-type responses [27] was very intuitive, as the range was demarcated by the most extreme positive and the most extreme negative options.

As for the construct validity, the factor analysis showed average QoLDAS scores ranging from 1.01 for Item 8–1.69 for Items 2 and 3, (and even 1.84 for Item 11, that was deleted afterwards) (Table 3). Hence, every reply was situated in the non-impact zone. Moreover, both the communalities extracted for the PCA, and the results obtained of the factor analysis support the conclusion that nine of the eleven items were well-represented in the factorization, making two of them (i.e., 'teeth position' and 'teeth colour') unnecessary in the final version of the questionnaire, as explained below (Table 3).

Results from the Bartlett's Sphericity test ($\chi^2 = 303.29$, 36gl; $p < 0.0001$) suggested the existence of a high number of inter-significant correlations among items and latent factors (or dimensions) of the QoLDAS. The KMO measure produced a global value of 0.67. Three components with eigenvalues above 1 emerged from the factor analysis of the QoLDAS and were supported by the elbow in the corresponding scree plot of eigenvalues. These three factors explained 71.9% of the total variance and were named according to the items loading (Table 3). Most items consistently and coherently loaded on a single factor. Table 3 presents the items with factorial weights greater than 0.5 ordered on three dimensions. According to previous findings, the items with factorial weights under 0.5 (i.e., 'teeth position' and 'teeth colour') were removed from the original version of the index (Table 3). For this reason, the final validated questionnaire has nine items and was re-named as 'QoLDAS-9' at this stage (Table 3). The first factor, called psycho-facial aesthetic dimension, was the most explanatory (24.8% of variance). This factor was formed by the combination of Items 4, 5, and 7 (improving the facial profile, improving the lip support, and feeling more self-confident, respectively). The second factor, named interactive aesthetic dimension comprised Items 3, 6, and 9 (would not change the prosthetic teeth, feeling younger, and improving the social relations, respectively). The third factor, which was designated as *socio-dental aesthetic* dimension, included Items 1, 2, and 8 (appropriate teeth size, appropriate length of the teeth during laughing, and having received congratulations because of the prosthetic rehabilitation, respectively) (Table 3).

The QoLDAS-9 total and dimensional scores exhibited inverse correlations with the total score of the OHIP-20sp. This implied that subjects with higher QoLDAS-9 scores (lower negative impact) tended to present lower OHIP-20sp scores. However, only the QoLDAS-9 total score ($p = 0.04$) and the score of its socio-dental aesthetic dimension ($p = 0.05$) demonstrated significant inverse correlations with the OHIP-20sp total score. Given that the qualitative interpretation of both tests coincided, the convergent validity of the QoLDAS-9 was confirmed (Table 4: convergent validity).

Among the psychological variables tested, two of the three *global oral satisfaction* measures reported by the patients (i.e., self-perceived satisfaction with the aesthetics and function) (Table 2) were found to positively modulate the QoLDAS-9 impact scores ($p < 0.001$). This fact confirmed adequate criterion validity for the created index (Table 2). Furthermore, the three VAS self-rated satisfaction measures were factors that directly influence the OARQoL ($p < 0.001$; Table 2).

Concerning the analysis of the discriminant validity of the new scale, the prosthodontic groups were neither discriminated by the total, nor by the dimensional scores of the QoLDAS-9 index (Table 4: discriminant validity). The prosthesis design yielded no significant differences despite the questionnaire used ($p > 0.05$) (Table 4: discriminant validity), so that CD and IO restorations provided statistically similar OARQoL and OHRQoL.

3.3. Analysis of the 'satisfaction with dental appearance' construct

The level of education (Group 1 of variables) was identified as the unique modulator of patients' satisfaction ($p = 0.02$) in this study. Those subjects having secondary or university education recorded the significantly lowest QoLDAS-9 scores and, thus, the least OARQoL (Table 1).

Table 4
Comparison of self-reported satisfaction with aesthetics among groups; and convergent and discriminant validity of the QoLDAS-9 index ($N = 70$).

	Impact of the prosthesis on the OARQoL			Convergent validity (correlation among OHIP-20sp and QoLDAS-9 total scores)	
	Mean (SD)	Difference between means	*p*-value	rho	*p*-value
QoLDAS-9 dimensional scores					
Psycho-facial aesthetics					
Group 1: CD ($n = 34$)	4.56 (2.41)	NS	0.16 NS[a]	−0.13	0.29
Group 2: IO ($n = 36$)	5.36 (1.57)				0.11
Interaction aesthetics					
Group 1: CD ($n = 34$)	3.74 (2.32)	NS	0.36 NS[a]	−019	0.11
Group 2: IO ($n = 36$)	3.39 (3.41)				
Socio-dental aesthetics					
Group 1: CD ($n = 34$)	3.44 (2.56)	NS	0.82 NS[a]	−0.23	0.05*
Group 2: IO ($n = 36$)	4.06 (3.91)				
Discriminant validity					
QoLDAS-9 total score					
Group 1: CD ($n = 34$)	11.74 (6.38)	NS	0.53 NS[a]	−0.24	0.04*
Group 2: IO ($n = 36$)	12.81 (7.77)				
OHIP-20sp total score					
Group 1: CD ($n = 34$)	8.44 (14.99)	NS	0.87 NS[a]	N/A	N/A
Group 2: IO ($n = 36$)	5.75 (9.92)				

Higher scores indicate major satisfaction with aesthetics. CD, complete dentures; IO, implant- retained overdentures; NS, not significant ($p > 0.05$); N/A, not applicable.
* Significant at $\alpha = 0.05$.
[a] Mann–Whitney U test.

The profile of the subjects obtaining lower QoLDAS-9 scores (i.e., poorer OARQoL) is that of a widower man over 75 years old (Group 1 of variables), who had worn his prosthesis in the mandible for more than five years, and used to visit the dentist yearly (Group 2 of variables) (Table 1). Nevertheless, these variables did not significantly affect the OARQoL.

4. Discussion

Dental appearance comprises an important aspect of oral health-related quality of life [39] that has been conceptualised by the authors as 'Oral aesthetic-related quality of life (OARQoL)'. In this cross-sectional study, for the first time, a scale containing explicit measures of OARQoL was created to determine the impact of the self-perception of dental aesthetics on the well-being of current and future prosthetically-restored edentulous patients. The new questionnaire, named 'Quality of Life associated with Dental Aesthetic Satisfaction (QoLDAS-9)' was validated for CD and IO users. The impact of both types of restorations on the OARQoL was also evaluated on the basis of survey-based data and clinical examination.

The face and content validity of the QoLDAS-9 was confirmed in the pilot trial: subjects understood the questionnaire and the items covered the main aspects of the theoretical 'satisfaction with dental appearance' construct [24,29].

In the main study, the Cronbach's α value [36] (which largely surpassed the recommended threshold of 0.7) [16,36,40,41], confirmed the reliability of the QoLDAS-9 (Table 3). Moreover, the bipolar measure configured by the matrix of items' responses was more complete than the exclusive evaluation of negative effects made by other instruments on QoL [24,42]. This is crucial, as most of the QoLDAS-9 items were perceived as positive events in this research (Table 3).

Relating to the construct validity, the multidimensionality of the QoLDAS-9 was evidenced by the exploratory factor analysis [24,37]. The global KMO value of 0.67 suggested the existence of underlying factors [24,42] and three statistically differentiated domains emerged from the scale (Table 3) This multidimensional structure is in accordance with the basic requirements to develop a questionnaire [9,13,14,43], because: (a) these three factors, domains, or dimensions explained the 71.9% of the total variance; (b) each factor was valued by more than two items (reducing the pernicious effect of an individual measure) [24,44]; and (c) the weights of the items on only one factor were in general excellent (>0.50), with the exception of two items: teeth position and teeth colour, with weights below 0.50 [24,45] (Table 3). Such items were therefore removed from the original version of the questionnaire. Vallittu et al. [46] reported that the elderly wish to have natural-looking teeth according to their age, as they assume that natural teeth significantly darken over time [46,47]. Moreover, the main aesthetic parameters related to teeth position [48–52] can be easily managed by dentists and technicians to create an attractive smile in case of removable acrylic dental prostheses. Berkey et al. [53] found that old dentate patients reported more frequent aesthetic complaints than did their edentulous counterparts. Therefore, the specific validation of the index for wearers of other types of prosthetic restorations in different populations (e.g., fixed prostheses for younger people) might require the re-incorporation of the abovementioned items, which will be confirmed or refused in future studies.

The convergent validity of the QoLDAS-9 questionnaire was supported by: (a) the logical inverse convergence [10,13,14,16] between the total scores of the QoLDAS-9 and the OHIP-20sp ($rho = -0.24$; $p = 0.04$); and (b) the significant inverse correlation among the socio-dental aesthetic dimension of the QoLDAS-9 and the total score of the OHIP-20sp ($rho = -0.23$; $p = 0.05$) (Table 4). These associations confirmed that both indices, validated in the same reference population [10], measured related constructs [9,13,14,26].

Consistent with previous investigations [9,10,13,14,16,24], the criterion validity of the QoLDAS-9 was proven by the positive significant correlation among its total score and the VAS punctuations of the *aesthetic* and *function* satisfaction variables (Table 2). Those patients who reacted positively to the aesthetic appearance and functionality of their restorations achieved significantly higher QoLDAS-9 scores, meaning higher OARQoL. It should be further analysed if a proper function of a dental prosthesis makes the patient feel more satisfied with its aesthetics, as it could be interpreted from these results. Maybe because of the amplitude of the VAS intervals, no significant differences were encountered among the aesthetic evaluation performed by the patients and by the researcher (Table 2). However, the VAS scores registered by the interviewer within the 'satisfied' category tended to be lower than those reported by the patients (Table 2). This may support the fact that the professionals tend to be more critical towards aesthetics than the patients themselves [1,54–57]. Even so, the patients' evaluation made from their own subjective perceptions may be decisive to verify their OARQoL [11]; which was significantly modulated by the three global oral satisfaction measures in the expected direction.

On the subject of the discriminant validity, the first null hypothesis formulated in the present research was confirmed, since the QoLDAS-9 did not significantly differentiate among the rehabilitations tested: CD and IO users showed comparable OARQoL as measured with the new index. Both prosthodontic groups also exhibited similar levels of OHRQoL as scored by the OHIP-20sp (Table 4). In agreement with related research on QoL questionnaires [8,10,24,58], the narrow differences in means among the study groups may help explain these findings (Table 4) [9,38]. Furthermore, besides that both types of rehabilitations can be aesthetically equivalent when they are well indicated and fabricated, the participants were not demanding dental care during the study, suggesting that most of them were pleased with their aesthetics and overall oral-related well-being [9].

Conversely, the findings require partial rejection of the second null hypothesis, because the level of education significantly influenced the self-perception of OARQoL (Table 1). Our study patients with secondary and university education reported significantly higher dissatisfaction with the esthetic appearance of their dentures (Table 1). Patients with higher education levels acquire more access to information and knowledge and, therefore, may be more concerned compared to patients with basic education. Actually, patients with higher education studies are more likely to exhibit concerns and anxieties about oral treatments [59]. However, the lack of investigations on OARQoL and the disparities among the study protocols make comparisons difficult.

Although the remaining study variables did not significantly affect the OARQoL, the profile of the subjects reporting the highest impact was that of a widower man over 75 years old, who had worn bimaxillary CD or IO for more than five years, and used to visit the dentist yearly (Table 1). Some authors have stated the independence of 'gender' in the subjective perception of oral-related well-being [31,60], whereas others report the opposite [1,8,16,17,46]. Age was not a modulator of QoL in the present research, which may be somewhat justified because of the reduced age range of the sample [22]. Being widower may lead to a psychologically depressive state with repercussion in the self-perception of QoL [57,61]. Mandibular prostheses have been rated to provide lower overall satisfaction [7], which has been reflected as a trend in this research (Table 1). In addition, wearing the denture for more than five years resulted in higher impacts (Table 1), as the prosthesis might suffer from wear or instability. The frequency of revisions

did not significantly modulate the OARQoL (Table 1) coinciding with other investigations on QoL [7]. Nevertheless, the effect and magnitude of these variables on aesthetic-related satisfaction should be further assessed.

The continuous evaluation of the well-being of dental patients allows verification that the needs of society are being met [62]. One limitation of this study was that the volunteers were recruited from a single university dental clinic. The uncontrolled confounding variables that are present in clinical trials might have also affected the results to some extent [63]. Nonetheless, the heterogeneity of the sample (Table 1) facilitates the extrapolation of the findings [7,8,28]. Also, the information obtained with the QoLDAS-9 indicator will be helpful in achieving more appropriate subject-oriented solutions taking into account the particular characteristics of edentulous patients in different populations [64,65].

5. Conclusions

Within the limitations of the current investigation, the following conclusions may be drawn:

1. The QoLDAS-9 index has suitable psychometric properties for assessing the impact of muco-supported complete dentures and implant-retained overdentures on the oral aesthetic-related well-being.
2. Both types of prosthetic rehabilitations tested (CD, IO) are predictable treatment options for improving the aesthetic self-perception and satisfaction of edentulous patients.
3. The self-reported aesthetic and functional satisfaction and the education level significantly modulated the OARQoL as evaluated by the QoLDAS-9. Therefore, perceiving a proper aesthetic appearance and functionality of the prosthesis and/or having a basic education might somewhat lead to a better OARQoL as measured with the new instrument.
4. The QoLDAS-9 has potential benefits for decision making in completely edentate subjects demanding prosthetic treatment, allowing for the supervision of the OARQoL of our patients over time.

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6.3. ARTÍCULO III: Carmen Perea, Arelis Preciado, Jaime Del Río, Christopher D. Lynch, Alicia Celemín, Raquel Castillo-Oyagüe. **Oral aesthetic-related quality of life of muco-supported prosthesis and implant-retained overdenture wearers assessed by a new, short, specific scale (QoLDAS-9).** Journal of Dentistry 2015; 43: 1337-45.

(Calidad de vida asociada a la estética oral de portadores de prótesis mucosoportadas y sobredentaduras implanto-retenidas, evaluada con una escala nueva, corta y específica (QoLDAS-9)).

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TRADUCCIÓN DEL RESUMEN

Objetivos: *Validar un nuevo cuestionario para evaluar la "Calidad de vida asociada a la estética dental" ('OARQoL') en pacientes rehabilitados protéticamente. El concepto de "OARQoL" evalúa el impacto de la autopercepción de la estética dental en el bienestar de los pacientes.* ***Métodos:*** *Se diseñó el índice "Calidad de Vida asociada con la Satisfacción respecto a la Estética Dental" ('QoLDAS') (Anexo 10.6). Tras el estudio piloto, se distribuyeron 70 pacientes en dos grupos dependiendo del tipo de rehabilitación prostodóntica: Grupo 1 (CD; n = 34): prótesis completas mucosoportadas, y Grupo 2 (IO; n = 36): sobredentaduras implanto-retenidas. Los pacientes respondieron las preguntas del QoLDAS-9 (Anexo 10.6) y del Perfil de Impacto de Salud Oral (OHIP-20sp) (Anexo 10.4), y puntuaron su satisfacción en una escala analógica visual (VAS). También se registraron las variables socio-demográficas y los factores relacionados con las prótesis. Se investigaron las propiedades psicométricas del QoLDAS. Las correlaciones entre ambos tests fueron exploradas mediante el test de Spearman. Se calculó la estadística descriptiva y se aplicaron tests no paramétricos para evaluar el efecto de las variables de estudio en la OARQoL (α = 0,05).* ***Resultados:*** *EL QoLDAS resultó ser fiable y válido. El análisis factorial confirmó la existencia de tres dimensiones y de inter-correlaciones significativas entre los nueve ítems que finalmente fueron incluidos en el cuestionario. Las dos escalas empleadas mostraron una correlación inversa entre sí. La autopercepción de* Satisfacción respecto a la Estética y la Función *y el* Nivel educacional *modularon significativamente la OARQoL según la evaluación efectuada con el QoLDAS-9.* ***Conclusiones:*** *El QoLDAS-9 confirmó su capacidad psicométrica para evaluar la OARQoL de los*

pacientes portadores de prótesis completas y de sobredentaduras implanto-retenidas. Ambos grupos mostraron niveles equiparablemente elevados de OARQoL. Grados de educación superiores conducen a inferiores valores de OARQoL. ***Significación clínica:*** *El QoLDAS-9 puede ser recomendado para anticipar el efecto de las restauraciones protéticas sobre el concepto de OARQoL. Tanto las prótesis completas mucosoportadas como las sobredentaduras implantológicas son opciones predecibles para mejorar la autopercepción estética de los pacientes edéntulos.*

Title: 'Oral aesthetic-related quality of life of muco-supported prosthesis and implant-retained overdenture wearers assessed by a new, short, specific scale (QoLDAS-9)'.

Short title: OARQoL measured by a new scale: the QoLDAS-9.

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Key words: Quality of Life associated with Dental Aesthetic Satisfaction (QoLDAS-9); Oral aesthetic-related quality of life (OARQoL); Oral health-related quality of life (OHRQoL); Oral Health Impact Profile (OHIP); Muco-supported prosthesis; Implant-retained overdenture.

7. DISCUSIÓN

7. DISCUSIÓN

La investigación desarrollada en la presente Tesis Doctoral se desglosa en tres estudios transversales en los que se utilizaron, en primer lugar, cuestionarios generales (OHIP) y específicos (QoLIP-10) ya diseñados, para, en una etapa ulterior, crear y validar un cuestionario que evaluara la influencia de la autopercepción de la estética oral en la calidad de vida de pacientes edéntulos rehabilitados protéticamente (tercer artículo). Por tanto, cada una de las tres etapas en las que se desarrolló la investigación ha quedado plasmada en un artículo de impacto publicado en revistas indexadas en el *Journal of Citation Reports* (J.C.R.).

7.1. Discusión de los resultados del primer artículo

Este trabajo describe la satisfacción general de pacientes portadores de prótesis completas convencionales mucosoportadas teniendo en cuenta los datos obtenidos en el estudio transversal y en el examen clínico. El tamaño de la muestra fue similar al de otros estudios que evalúan la influencia de la rehabilitación protética en la OHRQoL.[66] Los resultados obtenidos pueden ayudar a predecir el posible efecto de las prótesis completas en términos de bienestar de futuros pacientes subsidiarios de este tipo de tratamiento.

Aunque una limitación del protocolo de investigación es que los pacientes fueron reclutados únicamente en una clínica odontológica universitaria, debido a la variabilidad en el género, edad, estado civil, nivel de educación y hábitos conductuales de los voluntarios (Fig. 1, artículo 1) nuestros resultados podrían ser extrapolados a pacientes de otros países con perfiles socio-demográficos y clínicos comparables.

La escala genérica OHIP-14sp ha demostrado mejor rendimiento que otros cuestionarios[67] y mayor sensibilidad para detectar la insatisfacción en cuanto a la calidad de vida. Ha sido previamente aplicada en ensayos clínicos y estudios transversales con el fin de evaluar la efectividad de los tratamientos para el edentulismo,[38,68] por lo que su empleo en la presente investigación facilitó la comparación de los resultados. Por la misma razón, se eligió el umbral que considera como impacto la puntuación ≥ 2.[27, 69]

La versión validada en España del OHIP-14sp[27] se administró en forma de entrevista. A este respecto, mientras Souza y cols.[70] no reportaron diferencias en cuanto a la puntuación dependiendo de la forma de administración (auto-cumplimentado *vs.* entrevista), Ekanayake y Perera[71] hallaron tasas de cumplimentación más bajas y pérdidas de datos cuando el OHIP-14sp fue auto-completado.

Se consideró un periodo de un mes anterior a la hora de reportar los impactos en lugar de los doce meses que se utilizaron en la versión original del cuestionario.[26] Aunque el periodo no afecta la consistencia interna del OHIP, se estima que la memoria a corto plazo es más exacta para proporcionar una información fiable.[71]

La prevalencia de impacto obtenida en este estudio (23,5%) (Tabla 1, artículo 1), que es el porcentaje de sujetos que reportan al menos un ítem afectado de una manera ocasional o con más frecuencia (puntuación ≥ 2), es inferior a un tercio de la registrada en la población española.[27,69] Sin embargo, es significativo que, a diferencia de lo que ocurrió en estas investigaciones, nuestros pacientes eran mayores y no buscaban ningún tipo de tratamiento. Se ha concluido que, a mayor edad, mayor frecuencia de impactos, lo que se atribuye al tipo acumulativo de patología oral, como la caries dental o la enfermedad periodontal.[69] Sin embargo, el presente estudio se llevó a cabo en pacientes edéntulos, lo que puede explicar, hasta cierto punto, la ausencia de una correlación

directa entre la edad y la prevalencia de impacto oral. Relativo a la puntuación media total obtenida (19 ± 9,8), Emami y cols.[72] sugirieron que, aunque las dentaduras mandibulares implanto-retenidas pueden ser más satisfactorias para los pacientes edéntulos que las prótesis completas convencionales, la magnitud del efecto aún queda por determinar. Por lo tanto, hay una necesidad de evidencia adicional incluyendo el análisis del coste-efectividad en el impacto de las sobredentaduras mandibulares y las prótesis convencionales.

Las principales subescalas o dimensiones del OHIP-14sp que más incomodaron a los pacientes desdentados portadores de prótesis completa en este trabajo fueron "Limitación funcional" (Q1: dificultad al pronunciar; Q2: alteración del sentido del gusto), "Dolor físico" (Q4: incomodidad al comer alimentos) y "Dificultad física" (Q7: dieta insatisfactoria; Q8: interrupción de comidas) (Tabla 1, Figura 2, artículo 1). La alteración del gusto y el miedo a perder la prótesis comiendo o hablando son consecuencia de las limitaciones intrínsecas del tratamiento con prótesis completa, como la menor fuerza masticatoria, la retención y estabilidad comprometidas y el cubrimiento de las glándulas salivales menores palatinas.[70] Más allá de esto, De Oliveira y Frigerio[73] afirmaron que los usuarios de prótesis completa pueden ser más susceptibles a la malnutrición en comparación con los portadores de sobredentaduras.

Sin embargo, los dominios del OHIP-14sp que mostraron menor prevalencia de impacto en el presente estudio fueron "Dificultad social" (Q11: irritabilidad con los demás; Q12: dificultades para realizar actividades diarias), y "En desventaja/hándicap" (Q13: vida insatisfactoria; Q14: incapacidad de funcionar), que recibieron por unanimidad la respuesta (o frecuencia) "nunca" (Tabla 2, Figura 2, artículo 1). Esto indica una percepción positiva de ambas dimensiones, consistente con la tendencia observada por Slade y Spencer[26] cuando utilizaron la versión original del cuestionario

(OHIP-49) en una población comparable. Con respecto al sueño segmentado, muchos dentistas recomiendan quitar las prótesis durante la noche, ya que llevarlas constantemente podría incrementar el riesgo de irritaciones e infecciones. Sin embargo, alrededor del 10% de la población sufre apnea del sueño obstructiva (OSA) y dormir sin sus prótesis puede derivar en dificultades respiratorias aumentadas. Investigaciones recientes, sugieren que en pacientes con OSA, las ventajas de quitar las prótesis durante la noche deben ser ponderadas frente al riesgo de sufrir un colapso de las vías respiratorias altas.[74] Por lo tanto, este factor debería ser evaluado en mayor profundidad monitorizando a los pacientes para correlacionar la presencia de OSA con la puntuación obtenida en el ítem 9 del OHIP cuando los pacientes duermen con o sin sus prótesis.

La dimensión "En desventaja/hándicap" reveló la mejor satisfacción general con la existencia como concepto general y la habilidad en el desarrollo de la vida ordinaria cuando los pacientes portaban sus prótesis completas. Por tanto, ningún paciente en esta investigación se sintió incapaz de desarrollar sus funciones (Tabla 1, Figura 2, artículo 1). Además de una mayor tolerancia a la discapacidad por parte de los pacientes mayores,[75] es probable que la subjetividad de los individuos haya intervenido en la satisfacción registrada con respecto a este dominio.

En lo que respecta a los datos socio-demográficos y de hábitos de salud, los resultados obtenidos en esta investigación indican que no hay diferencias significativas, aunque parece existir una marcada tendencia a percibir una menor satisfacción en el caso de los pacientes edéntulos varones, como describieron Slade y Spencer[26] (Tabla 2, artículo 1). De acuerdo con estudios previos realizados por McGrath[75] en U.K y por Montero[69] en España, los pacientes con *Nivel educacional* alto mostraron mayores impactos, aunque sin diferencias significativas con respecto a aquellos que poseían educación básica (Tabla 2, artículo 1). Ni la *Edad* ni el *Estado civil* parecen ser

moduladores de la OHRQoL (Tabla 2, artículo 1), sin embargo estos factores precisan más investigación ya que no se encontraron estudios que los hubieran analizado anteriormente. Asimismo, nosotros no hallamos diferencias significativas en pacientes *Fumadores* o *Consumidores habituales de alcohol*, si bien dichos hábitos se asociaron a mayores porcentajes de impacto según los hallazgos de Lin y cols.[76]

Con referencia a los datos relacionados con la prótesis, los portadores de prótesis completas *inferiores* obtuvieron una satisfacción general menor (Tabla 3, artículo 1), proporcionando significativamente mayor impacto en las dimensiones de "Limitación funcional" y "Dolor físico". Esto podría atribuirse al patrón de reabsorción centrífuga de la mandíbula, que influye en la retención y estabilidad de las prótesis, pudiendo afectar al soporte osteomucoso sobre todo en rebordes alveolares planos,[77] como indicaron Fenlon y Sheriff.[78] Además, la mucosa móvil y no queratinizada ofrece una menor resistencia al trauma, derivando en úlceras con mayor incidencia, lo que produce mayores impactos en estos pacientes.[79]

Considerando el *Tratamiento protético antagonista*, la prevalencia de mayor impacto corresponde a pacientes portadores de prótesis completas en ambas arcadas, mostrando diferencias significativas con respecto a los otros subgrupos (Tabla 3, artículo 1). En concordancia con Hogenius y cols.,[80] la mayor satisfacción corresponde a los pacientes portadores de rehabilitaciones fijas sobre implantes como antagonista. Este hecho confirma las aseveraciones de Awad y cols.[68] que encontraron que los tratamientos sobre implantes mejoran significativamente la OHRQoL en comparación con las prótesis convencionales.

Como en investigaciones anteriores,[66] los pacientes que requirieron *Reparación o cambio* de sus prótesis tienden a expresar menos satisfacción (Tabla 3, artículo 1), así como aquéllos que eran edéntulos o portadores de prótesis por menos de cinco años (por

el tiempo de adaptación a las prótesis); si bien dichas diferencias no fueron significativas (Tabla 3, artículo 1).

Con respecto a la exploración clínica, la *Sensación de boca seca* produce impactos mayores en la calidad de vida de los pacientes ya que la saliva desempeña un papel importante en la retención y confort de las prótesis removibles. Sin embargo, no se detectaron diferencias significativas. Conforme a la literatura,[81] en nuestra investigación los pacientes que referían boca seca estaban sometidos a medicación para problemas de tiroides, hipertensión, parkinson, epilepsia o cáncer de próstata; tratamientos causantes de dicho efecto.

Respecto a la influencia de la *Candidiasis*, sí que se encontraron diferencias significativas, no presentando impacto aquellos pacientes que la padecían. Este hallazgo puede explicarse porque, dado que todos los participantes en los que encontramos estomatitis protética sufrían enfermedades graves, la percepción psicológica de incomodidad con las prótesis quedaba relegada a un segundo plano.[81] Sin embargo, este aspecto requiere futuras validaciones, ya que hasta la fecha no hay estudios que correlacionen la presencia de enfermedades graves y farmacoterapia con el nivel de impacto en la OHRQoL.

En este estudio la satisfacción con el aspecto estético y la capacidad masticatoria eran comparativamente mejores en el caso de la mayoría de los pacientes restaurados que habían llevado con anterioridad otra prótesis convencional. Dichos resultados están en concordancia con los obtenidos previamente con el cuestionario OHIP-14sp,[27] ya que la habilidad masticatoria es uno de los determinantes de la satisfacción mejor asociados con OHRQoL.[82]

7.2. Discusión de los resultados del segundo artículo

En el segundo artículo se validó un cuestionario específico para implantoprótesis en usuarios de prótesis implantológicas cementadas. En esta investigación, la hipótesis probada fue que el tipo de restauración implantosoportada (cementada o atornillada) no condiciona el nivel de satisfacción de los pacientes; y que la satisfacción de usuarios de prótesis implantosoportada no depende de las variables socio-demográficas, comportamientos relacionados con la salud, y/o hábitos concernientes a las prótesis.

Pese al progresivo desarrollo de prótesis sobre implantes más predecibles,[83] el uso de técnicas de medición de resultados centradas en el paciente pueden ser útiles para facilitar una solución rehabilitadora más adecuada.[84,85] En este artículo, se seleccionó el cuestionario QoLIP-10, diseñado y validado previamente por el equipo de investigación con el que colabora la doctoranda para portadores de implantoprótesis. Dicho cuestionario es el único índice creado internacionalmente de forma específica para usuarios de rehabilitaciones sobre implantes, pero aún no había sido validado para portadores de restauraciones implantosoportadas cementadas, por lo que en el presente artículo acometimos dicha tarea. Por tanto, a través de un estudio de corte transversal y un examen clínico evaluamos el impacto de las restauraciones cementadas y atornilladas en la satisfacción del paciente.

Los resultados requieren el rechazo de la hipótesis nula ya que: *1)* el tipo de restauración fija sobre implantes influye en el nivel de satisfacción del paciente y *2)* diversas variables de estudio modulan la calidad de vida asociada a la salud oral de los portadores de prótesis sobre implantes cementadas y atornilladas. Una limitación de este estudio es que los pacientes fueron reclutados en una sola clínica odontológica universitaria. Otras posibles variables de confusión, inherentes a cualquier ensayo clínico, podrían haber afectado los resultados hasta cierto punto.[86] Sin embargo, la

heterogeneidad de la muestra (Tabla 1, artículo 2) facilita la extrapolación de los resultados.[34,37,38]

Teniendo en cuenta que los sujetos que participaron en el estudio piloto comprendieron la totalidad del cuestionario y que el instrumento no carecía de contenido importante, se confirmaron la validez de contenido y la validez aparente del QoLIP-10.[26,87,88]

En el estudio principal, la fiabilidad del QoLIP-10 fue ratificada por un alto valor alpha de Cronbach[50] en los grupos evaluados (Tabla 2, artículo 2). La consistencia interna del índice fue demostrada por una fuerte correlación entre la puntuación total y las puntuaciones dimensionales del QoLIP-10 (Tabla 3, artículo 2).[44,50] Además, los diez ítems del QoLIP-10 superaron el umbral de 0,2 en la matriz de correlación ítem-total, que es un requisito básico para la inclusión de un ítem en un test.[44] Finalmente, la medición bipolar configurada por la matriz de respuestas de los ítems que se utilizó en este estudio es más completa que la evaluación exclusiva de efectos negativos del OHIP-14 (entre otros).[88,89] Teniendo en cuenta que la mayoría de los ítems del QoLIP-10 fueron percibidos como eventos positivos en este trabajo, se trata de un aspecto esencial (Tabla 3, artículo 2).

De acuerdo con investigaciones previas,[28,88,90] se probó la validez de criterio del QoLIP-10, ya que su puntuación total se correlacionó positivamente con todas las variables de satisfacción (Tablas 1 y 3, artículo 2). Los pacientes que estaban satisfechos con su estética, masticación y restauraciones implantosoportadas[91] alcanzaron, significativamente, las mayores puntuaciones en el QoLIP-10, lo que se traduce en una mayor calidad de vida (Tabla 1, artículo 2). Estos resultados concuerdan con investigaciones previas desarrolladas en usuarios de implantoprótesis que utilizaban el índice QoLIP-10.[28,29] En su estudio retrospectivo, Vermylen y cols.[92] registraron una

respuesta positiva por parte de los pacientes para las variables estética y satisfacción en el caso de restauraciones implantosoportadas unitarias. En el trabajo de Pjetursson y cols.,[93] en el que se aplicaban 13 preguntas con una escala visual analógica (VAS), la mayoría de los pacientes (> 90%) se mostraron completamente satisfechos con la función masticatoria y la estética. Desafortunadamente, las diferencias en el protocolo (número de implantes, diseño de las prótesis, tipo de cuestionario aplicado, variables registradas, etc.) dificultan las comparaciones.

En cuanto a la validez de constructo, la multidimensionalidad del QoLIP-10 se puso de manifiesto con el análisis factorial exploratorio, que mostró tres dimensiones emergentes estadísticamente diferenciadas (Tabla 2, artículo 2). De acuerdo con estudios anteriores,[8,28,29,94] se obtuvo una estructura simple, ya que cada ítem fue ponderado en gran medida sobre una sola dimensión (Tabla 2, artículo 2). La validez convergente del QoLIP-10 fue soportada por: *a)* la lógica convergencia inversa (*rho* = – 0,36, p <0,001) entre las puntuaciones totales del QoLIP-10 y el OHIP-14sp;[28,29,44,88,95] y *b)* las correlaciones significativas inversas entre la puntuación total de cada cuestionario y algunas puntuaciones dimensionales de ambas pruebas (Tabla 3, artículo 2). Estas asociaciones confirmaron que ambos cuestionarios evaluaron el mismo constructo.[44] Esto es importante, ya que el OHIP-14sp ha sido recientemente validado en la misma población referencia.[27]

En cuanto a la validez discriminante, la dimensión "Rendimiento funcional" del QoLIP-10 discriminó significativamente entre los grupos de estudio (Tabla 4, artículo 2). Este índice atribuyó la peor satisfacción a los portadores de prótesis cementadas sobre 3-5 implantes, con diferencias significativas respecto a los restantes grupos evaluados. El dominio "Discapacidad física" del cuestionario OHIP-14sp mostró los mismos resultados (Tabla 4, artículo 2). Por tanto, tanto la extensión como el tipo de

retención de las prótesis sobre implantes pueden condicionar la autopercepción de la calidad de vida del paciente. Varios autores,[96-98] confirmaron una capacidad discriminatoria disminuida con las restauraciones sobre implantes debido a la ausencia de ligamento periodontal, que se considera esencial para la función táctil oral.[99,100] De acuerdo con estas afirmaciones, Chaar y cols.[101] recomendaron rehabilitar brechas edéntulas largas y arcadas completas con prótesis atornilladas. Dado que a mayor extensión de la restauración, mayor probabilidad de complicaciones, la recuperabilidad de las implantoprótesis atornilladas puede ser menos traumática y más predecible en estos casos, en comparación con los sistemas cementados.[101]

Al contrario que en estudios previos que utilizaron el QoLIP-10,[29] los grupos evaluados fueron discriminados por la puntuación total de este índice (Tabla 4, artículo 2). La mejor calidad de vida correspondió a las prótesis cementadas soportadas por dos implantes. La falta de chimeneas en las prótesis cementadas proporciona un diseño que mejora la resistencia física de la porcelana, originando menores tasas de fractura.[102-104] Asimismo, los contactos antagonistas en el composite oclusal que cubre las chimeneas son inestables a largo plazo.[105] La pérdida de composite puede resultar en un mayor número de visitas al dentista, lo que provoca un mayor impacto en el bienestar del paciente. Además, las chimeneas en la superficie oclusal proporcionan una estética escasa y pueden no cumplir con las expectativas del paciente, incluso en caso de restauraciones cortas.[102]

Aunque no se identificaron diferencias significativas en cuanto a las variables socio-demográficas, el perfil de los sujetos que revelaron el menor confort psicológico correspondió a una mujer soltera, con educación básica o educación especial; lo que fue detectado por ambos cuestionarios (Tabla 1, artículo 2). Las diferencias psicológicas entre hombres y mujeres podrían ayudar a explicar el posible efecto de la variable

Género en la satisfacción del paciente, ya que la percepción de los individuos se ve influida con mayor intensidad por la auto-evaluación que por parámetros objetivos.[106] Los pacientes con mayor *Nivel educacional* mostraron mayor satisfacción con respecto a los sujetos que poseían educación básica (Tabla 1, artículo 2). Esta tendencia fue anunciada por Preciado y cols.[29] en el caso de usuarios de prótesis atornilladas. La *Edad* no fue un factor modulador del bienestar (Tabla 1, artículo 2), lo que está en consonancia con un estudio llevado a efecto en portadores de prótesis completas y conducido en la misma población referencia.[37] Como en investigaciones anteriores,[29,37] los pacientes solteros tendieron a expresar menos satisfacción general que aquéllos que estaban casados, hallazgo que debería ser analizado en profundidad en futuros estudios.

No se encontraron diferencias significativas cuando se cruzaron las puntuaciones del QoLIP-10 con las variables de salud (Tabla 1, artículo 2). Sin embargo, se asoció una mejor calidad de vida a una mayor *Frecuencia de cepillado*, lo que enfatiza la importancia de enseñar a los pacientes hábitos de salud oral[95] (Tabla 1, artículo 2). Evidentemente, los pacientes que expresaban *Quejas sobre su boca* reportaron de forma significante menor calidad de vida, lo que concuerda con la literatura[34,37,38] (Tabla 1, artículo 2).

Las propiedades psicométricas del cuestionario QoLIP-10 para estimar el efecto de las prótesis implantológicas cementadas sobre el bienestar de los pacientes pueden ser relevantes en la toma de decisiones, la medición de los resultados clínicos y para fines de investigación. En nuestro estudio, la satisfacción del paciente depende de la extensión y tipo de retención de la restauración fija sobre implantes, lo que está en consonancia con investigaciones previas.[107,108] Particularmente, las restauraciones cortas cementadas sobre implantes conducen a una mejor auto-percepción de la calidad de vida de los pacientes respecto a las prótesis atornilladas.

7.3. Discusión de los resultados del tercer artículo

En el tercer artículo se desarrolló un nuevo cuestionario para evaluar la "Calidad de vida asociada a la estética dental" ('Oral aesthetic-related quality of life: OARQoL') de pacientes edéntulos rehabilitados protéticamente. La primera hipótesis fue que el tipo de restauración (prótesis completa o sobredentadura implantológica) no condiciona el nivel de satisfacción de los pacientes. Como segunda hipótesis planteamos que la calidad de vida de los portadores de dichas prótesis no depende de variables socio-demográficas, comportamientos de salud, y/o hábitos relacionados con las restauraciones. Los resultados del estudio confirmaron que el tipo de rehabilitación no influenciaba el grado de bienestar de los pacientes. Sin embargo, algunas variables analizadas modularon la OHRQoL de los sujetos.

Por consiguiente, en este tercer estudio transversal se diseñó, por primera vez, un cuestionario específico (test) para medir la OARQoL, término propuesto por los autores. Dicha escala contiene medidas específicas para determinar el impacto de la percepción de la estética oral en el bienestar tanto de pacientes edéntulos actuales como futuros restaurados con prótesis dentales. Este nuevo cuestionario llamado "Calidad de vida asociada con la satisfacción respecto a la estética dental" ('QoLDAS-9') ha sido validado en esta investigación para pacientes portadores de prótesis completas y sobredentaduras retenidas por implantes. El impacto de ambos tipos de restauraciones en la OARQoL se evaluó también en base a un examen clínico y al análisis de posibles factores moduladores.

La validez aparente y de contenido del QoLDAS-9 fueron confirmadas en el estudio piloto: los participantes comprendían todos los ítems del cuestionario y no faltaba contenido relevante acerca de la satisfacción con la apariencia dental.[87,88]

En el estudio principal, el valor de alpha de Cronbach[50] (que superó ampliamente el umbral recomendado de 0,7)[27,50,89,109] confirmó la fiabilidad del índice (Tabla 3, artículo 3). Además, la medición bipolar que se empleó, configurada por la matriz de respuestas de los ítems, es más completa que las escalas de medición que se limitan a valorar la presencia de efectos negativos de otros instrumentos de calidad de vida.[88,110] Este aspecto es muy importante, ya que la mayoría de los ítems del QoLDAS-9 fueron percibidos como eventos positivos en este estudio (Tabla 3, artículo 3).

En cuanto a la validez de constructo, el análisis factorial exploratorio demostró la multidimensionalidad del instrumento QoLDAS-9.[47,88] El valor de KMO *(Kaiser-Meyer-Olkin)* contrasta si las correlaciones parciales entre las variables son suficientemente pequeñas.[62,63] En este estudio, el KMO de 0,67 sugiere la existencia de factores subyacentes y de tres subescalas independientes claramente diferenciadas en términos estadísticos[47,88] (Tabla 3, artículo 3). Esta estructura multidimensional se corresponde con los requerimientos básicos para desarrollar un cuestionario por tres motivos [9,28,29,111] : *a)* las tres dimensiones o subescalas explican el 71,9% de la varianza total; *b)* cada dominio fue valorado por más de dos ítems (reduciendo el efecto pernicioso de una medida individual);[88,112] y *c)* el peso de los ítems en una dimensión única fue en general excelente (> 0,50) con excepción de dos ítems: "posición dental" y "color", que no alcanzaron dicho peso[88,113] (Tabla 3, artículo 3). Por este motivo, ambos ítems se eliminaron del cuestionario. Este hecho podría explicarse porque, en palabras de Vallittu y cols.,[114] las personas mayores desean tener una apariencia dental acorde con su edad, y asumen que el color de sus dientes va oscureciendo con los años.[114,115] Por otra parte, actualmente es sencillo modificar los principales parámetros estéticos relativos a la posición dental para crear una sonrisa atractiva en el caso de las prótesis removibles.[116-120] Berkey y cols.[121] afirman incluso que los pacientes dentados mayores

reportan más quejas relativas a la estética que los rehabilitados protéticamente. En definitiva, la futura validación del índice para portadores de otro tipo de restauraciones prostodóncicas podría requerir la re-incorporación o la eliminación de estos ítems.

La validez convergente del cuestionario QoLDAS-9 se confirmó por *a)* la lógica correlación inversa[27,29,36,111] entre la puntuación total del QoLDAS-9 y el OHIP-20sp (*rho* = -0,24; *p* = 0,04); y *b)* la inversa correlación significativa entre la dimensión socio-dental estética y la puntuación total de OHIP-20sp (*rho* = -0,23; *p* = 0,05) (Tabla 4, artículo 3). Estas asociaciones confirman que ambos índices, validados en la misma población de referencia,[36] miden el mismo constructo.[28,29,44,111]

En consonancia con investigaciones previas,[27,28,29,36,88,111] la validez de criterio del QoLDAS-9 se confirmó por la correlación significativa positiva entre su puntuación total y la puntuación de la escala VAS para las variables estética y función (Tabla 2, artículo 3). Por tanto, aquellos participantes que manifestaron estar satisfechos con su estética y función masticatoria obtuvieron puntuaciones significativamente mayores en el QoLDAS-9, y, por tanto, revelaron una mejor calidad de vida. En futuros estudios, debería valorarse si una mejor función de la restauración protética puede variar la autopercepción de su estética, tal y como se puede interpretar a partir de estos resultados. Las diferencias en cuanto a la valoración estética de las prótesis por parte del investigador y del paciente también fueron analizadas. Posiblemente por la amplitud de los intervalos de la escala VAS, no se encontraron diferencias significativas entre las evaluaciones de los pacientes y del investigador (Tabla 2, artículo 3). Sin embargo, la puntuación del investigador tiende a ser menor que la de los pacientes (Tabla 2, artículo 3). Este hallazgo puede explicarse por el hecho de que los profesionales suelen ser más críticos que los pacientes con respecto a la estética.[20,93,122-124] Aun así, la evaluación subjetiva de los pacientes es decisiva para valorar la calidad de vida asociada a la

autopercepción de la estética oral,[26] que fue significativamente modulada por las variables de satisfacción oral en la dirección esperada.

En cuanto a la validez discriminante, se confirmó la primera hipótesis nula formulada en esta investigación, ya que el nuevo cuestionario no encontró diferencias significativas entre las rehabilitaciones testadas. Ambos grupos también mostraron niveles similares de calidad de vida según la medición del OHIP-20sp (Tabla 4, artículo 3). De acuerdo con investigaciones precedentes,[28,36,88,126] esto puede explicarse por las estrechas diferencias entre las puntuaciones medias registradas en los grupos protéticos (Tabla 4, artículo 3).[28,90]

Independientemente de que ambos tipos de rehabilitación puedan ser equivalentes en términos de estética, los participantes no eran demandantes de atención dental durante el estudio, y, como consecuencia, la mayor parte de ellos estaban satisfechos con su estética y bienestar oral.[28]

También se analizó el efecto modulador de las variables de estudio en la calidad de vida asociada con la satisfacción respecto a la estética oral. A diferencia de lo que ocurría con la primera hipótesis nula, los resultados hallados con respecto a dichas variables conducen al rechazo parcial de la segunda hipótesis nula propuesta en esta investigación, ya que el *Nivel de educación* influyó significativamente en la calidad de vida asociada a la autopercepción de la estética oral (Tabla 1, artículo 1). En nuestro estudio, los pacientes con educación secundaria y universitaria reportaron significativamente mayor insatisfacción con la apariencia estética de sus prótesis. Los pacientes con mayor nivel educacional tienen mayor acceso a información y conocimientos y, por tanto, pueden estar más preocupados que los pacientes con educación básica. De hecho, los pacientes con estudios superiores son más propensos a exhibir preocupaciones y ansiedad con respecto a los tratamientos orales.[126] Sin

embargo, la falta de investigaciones similares a la nuestra y las consecuentes diferencias en los protocolos de investigación complican las comparaciones, especialmente en el caso de este artículo, por su carácter tan novedoso.

Por último, también se evaluaron otros resultados clínicamente relevantes. A pesar de que el resto de las variables de este estudio no afectaron significativamente a la calidad de vida, el perfil de los sujetos que reportaron el mayor impacto fue el de un hombre viudo de 75 años, portador de prótesis completa o sobredentadura bimaxilar durante más de 5 años y que visita al dentista anualmente (Tabla 1, artículo 3). Algunos autores han manifestado la independencia del *Género* en la percepción subjetiva del bienestar oral,[68,74] mientras que otros han sugerido lo contrario.[20,27,38,114,127] En cuanto a la *Edad*, no fue un factor modulador de la calidad de vida en esta investigación, lo que puede ser justificado por el reducido rango de edad de la muestra.[128] Además, ser viudo puede conducir a un estado depresivo con repercusión en la percepción de calidad de vida.[124,129] Las prótesis mandibulares proporcionan una menor satisfacción general,[37] lo que se ha reflejado como una tendencia en esta investigación (Tabla 1, artículo 3). Adicionalmente, llevar la prótesis durante más de cinco años genera impactos más elevados (Tabla 1, artículo 3), ya que la rehabilitación puede sufrir desgaste o inestabilidad. La *Frecuencia de revisiones* no modula significativamente la calidad de vida asociada con la satisfacción respecto a la estética oral (Tabla 1, artículo 3), en línea con otras investigaciones relacionadas.[37] Sin embargo, el efecto y magnitud de estas variables en la OARQoL debe ser evaluado en profundidad en futuras investigaciones.

La evaluación continua de la satisfacción de los pacientes dentales permite verificar que las necesidades de la sociedad están siendo satisfechas.[130] Una vez más, una limitación de este estudio es que los pacientes fueron reclutados en una sola clínica odontológica universitaria. Como en ocasiones anteriores, las variables de confusión no

controladas que están presentes en los ensayos clínicos, podrían haber afectado los resultados hasta cierto punto.[86] Sin embargo, la heterogeneidad de la muestra (Tabla 1, artículo 3) facilita la extrapolación de los hallazgos.[34,37,38] Por último, la información obtenida con el instrumento QoLDAS-9 será útil para lograr soluciones individualizadas más apropiadas, considerando las características particulares de los pacientes edéntulos en diferentes poblaciones.[84,85]

8. CONCLUSIONES

8. CONCLUSIONES

Dentro de las limitaciones de la investigación desarrollada a lo largo de los tres artículos que componen esta Tesis Doctoral se pueden extraer las siguientes conclusiones:

- El uso de prótesis completas convencionales proporciona impactos negativos en el nivel de OHRQoL de pacientes mayores, principalmente en caso de portadores de prótesis completas inferiores que requieren ser reparadas o sustituidas siendo el antagonista otra prótesis completa. La presencia de enfermedades graves, algunas de las cuales cursan con estomatitis, puede condicionar la autopercepción de incomodidad con las prótesis (considerando que dichos pacientes suelen medicarse con analgésicos diariamente), razón por la cual los pacientes con estomatitis mostraron mayor satisfacción en este estudio. En general, los dominios con más impacto en la calidad de vida de pacientes edéntulos rehabilitados con prótesis completa utilizando el cuestionario OHIP-14sp fueron “Limitación funcional” y “Dolor”.

- El índice QoLIP-10 demostró cualidades psicométricas adecuadas para valorar la OHRQoL de portadores de implantoprótesis fijas cementadas. La extensión y el tipo de retención de la restauración (cemento o tornillo) modulan la satisfacción del paciente. Las prótesis fijas cementadas sobre dos implantes parecen garantizar una mayor calidad de vida. No obstante, la peor autopercepción en el dominio “Rendimiento funcional” de dicho cuestionario corresponde a las implantoprótesis cementadas con más de dos implantes.

- El nuevo cuestionario diseñado, llamado QoLDAS-9, confirmó su validez y fiabilidad para evaluar el impacto de las prótesis completas y las sobredentaduras implantológicas en el bienestar relacionado con la estética oral (OARQoL). Ambos diseños protéticos son equiparables en términos de OARQoL, siendo igualmente predecibles para mejorar la satisfacción estética del paciente edéntulo. La variable *Nivel educacional* condiciona significativamente la OARQoL, aunque de forma inversa.

- Como conclusiones esenciales de esta Tesis, por primera vez internacionalmente: *a)* se ha validado el cuestionario QoLIP-10 para evaluar la calidad de vida asociada al estado de salud oral en usuarios de implantoprótesis cementadas; y *b)* se ha creado y validado el índice QoLDAS-9 para registrar el nivel de satisfacción relacionado con la autopercepción de la estética del tratamiento restaurador por parte de nuestros pacientes. Dichos índices permitirán anticipar el impacto de futuras rehabilitaciones sobre la sensación de calidad de vida de los pacientes, lo que estará vinculado a ciertas características personales de los mismos y resultará esencial a la hora de planificar un tratamiento exitoso.

9. REFERENCIAS

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10. ANEXOS

10.2. Modelo de consentimiento informado

CONSENTIMIENTO INFORMADO PARA EL PROYECTO DE INVESTIGACIÓN:

"Estudio del impacto en la calidad de vida del paciente subsidiario de tratamiento prostodóntico mediante el desarrollo y la aplicación de índices específicos"

- **Investigadora principal:**

Raquel Castillo de Oyagüe (Prof. Contratada Doctora, Departamento de Prótesis Bucofacial, U.C.M.)

- **Investigadora colaboradora:**

Carmen Perea Urbano (Investigadora. Departamento de Prótesis Bucofacial, U.C.M)

El equipo de investigadores identificados anteriormente, pertenecientes al Departamento de Prótesis Bucofacial de la Universidad Complutense de Madrid (U.C.M) ha planificado llevar a cabo una investigación mediante cuestionarios para evaluar el impacto causado por el tratamiento mediante diferentes tipo de prótesis en el bienestar de los pacientes.

Si usted decide participar en este proyecto, se le pedirá que complete un cuestionario, que es completamente voluntario. Algunas de las preguntas pueden parecer muy personales y usted se puede sentir incómodo compartiendo esta información con nosotros. Si usted lo desea puede dejar de contestar a cualquier pregunta.

Estamos obligados por ley a proteger su información, por lo tanto a cada cuestionario se le asignará un número por orden de asistencia, manteniendo así el anonimato de cada paciente. Únicamente el equipo de investigación que trabaja en este proyecto dispondrá de acceso a este cuestionario, y siempre se preservará su anonimato.

Se realizará también una exploración visual de diferentes aspectos de su prótesis y de su mucosa y reborde alveolar. Si como consecuencia de dicha exploración se observara la necesidad de cambiar o reparar su prótesis, el equipo de investigación únicamente está autorizado a derivarlo al servicio pertinente que se pondrá en contacto con usted a la mayor brevedad posible.

Asimismo, si se detectara cualquier tipo de patología, el equipo de investigación le informará del diagnóstico y las alternativas terapéuticas, incluyendo posibles interconsultas con cualquier otro servicio médico si los Doctores lo estimaran oportuno.

Yo, D./Dª._____,

A través del presente consentimiento, **DECLARO Y MANIFIESTO**, en pleno uso de mis facultades mentales, libre y espontáneamente, lo siguiente:

1. He leído y comprendo la información de este consentimiento.
2. Estoy de acuerdo en participar en este proyecto.
3. Puedo dejar de contestar cualquier pregunta si así lo deseo.
4. Otorgo mi consentimiento al Doctor/es y por ende al equipo de investigación del que forman parte, a realizar el cuestionario y la exploración clínica de la que he sido informado, en el marco del proyecto de investigación en el que voy a colaborar, de modo que podré retirar el presente consentimiento por escrito cuando así lo desee.

En Madrid, a _____de _____de 201_

PACIENTE:

FIRMADO DON/DOÑA_____

D.N.I. Nº_____

DOCTOR / INVESTIGADOR:

FIRMADO DON/DOÑA_____

D.N.I. Nº_____

COLEGIADO Nº_____

10.3a. Cuestionario OHIP-14sp (en español)

** Por favor indique su grado de acuerdo con las siguientes afirmaciones y proporcione la puntuación adecuada en cada caso:*

Perfil de Impacto de Salud Oral (OHIP-14sp)		**Nunca (0)**	**Rara vez (1)**	**Ocasionalmente (2)**	**Algunas veces (3)**	**Muchas veces (4)**
		Puntuación por ítem y por dimensión*				
D1.	***LIMITACIÓN FUNCIONAL***					
1.	¿Tiene dificultad para pronunciar algunas palabras debido a problemas con sus dientes, boca o prótesis?					
2.	¿Ha notado que su sentido del gusto ha empeorado debido a problemas con sus dientes, boca o prótesis?					
D2.	***DOLOR FÍSICO***					
3.	¿Ha sufrido molestias dolorosas en su boca?					
4.	¿Se ha encontrado incómodo al comer algún alimento por problemas con sus dientes, boca o prótesis?					
D3.	***MALESTAR PSICOLÓGICO***					
5.	¿Se ha sentido preocupado por problemas con sus dientes, boca o prótesis?					
6.	¿Ha estado estresado por problemas con sus dientes, boca o prótesis?					
D4.	***DIFICULTAD FÍSICA***					
7.	¿Ha llevado una dieta insatisfactoria por problemas con sus dientes, boca o prótesis?					
8.	¿Ha tenido que interrumpir comidas por problemas con sus dientes, boca o prótesis?					
D5.	***DIFICULTAD PSICOLÓGICA***					
9.	¿Ha encontrado dificultad para descansar por problemas con sus dientes, boca o prótesis?					
10.	¿Se ha sentido avergonzado por problemas con sus dientes, boca o prótesis?					
D6.	***DIFICULTAD SOCIAL***					
11.	¿Ha estado irritable con otras personas por problemas con sus dientes, boca o prótesis?					
12.	¿Ha tenido dificultad para realizar sus actividades diarias por problemas con sus dientes, boca o prótesis?					
D7.	***EN DESVENTAJA/HÁNDICAP***					
13.	¿Ha sentido que su vida es, en general, menos satisfactoria debido a problemas con sus dientes, boca o prótesis?					
14.	¿Se ha sentido totalmente incapaz de funcionar debido a problemas con sus dientes, boca o prótesis?					
Puntuación total del OHIP-14*						

* La puntuación total y la puntuación de cada dimensión será la suma de los marcajes de los respectivos ítems.

Cuanto mayor sea la puntuación total, menor será la satisfacción del paciente.

D1, D2, D3, D4, D5, D6 y D7: dimensiones del índice OHIP-14sp.

10.3b. Cuestionario OHIP-14 (en inglés)

** Please indicate your level of agreement with the following statements and give the appropriate score in each case:*

Oral Health Impact Profile (OHIP-14)		**Never (0)**	**Hardly ever (1)**	**Occasionally (2)**	**Fairly often (3)**	**Very often (4)**
				Item and dimensional scores*		
D1.	***FUNCTIONAL LIMITATION***					
1.	Have you had trouble pronouncing any words because of problems with your teeth, mouth or prostheses?					
2.	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or prostheses?					
D2.	***PHYSICAL PAIN***					
3.	Have you had painful aching in your mouth?					
4.	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or prostheses?					
D3.	***PSYCHOLOGICAL DISCOMFORT***					
5.	Have you been self conscious because of your teeth, mouth or prostheses?					
6.	Have you felt tense because of problems with your teeth, mouth or prostheses?					
D4.	***PHYSICAL DISABILITY***					
7.	Has your diet been unsatisfactory because of problems with your teeth, mouth or prostheses?					
8.	Have you had to interrupt meals because of problems with your teeth, mouth or prostheses?					
D5.	***PSYCHOLOGICAL DISABILITY***					
9.	Have you found it difficult to relax because of problems with your teeth, mouth or prostheses?					
10.	Have you been embarrassed because of problems with your teeth, mouth or prostheses?					
D6.	***SOCIAL DISABILITY***					
11.	Have you been irritable with other people because of problems with your teeth, mouth or prostheses?					
12.	Have you had difficulty performing daily activities because of problems with your teeth, mouth or prostheses?					
D7.	***HANDICAP***					
13.	Have you felt that life is less satisfying because of problems with your teeth, mouth or prostheses?					
14.	Have you felt totally unable to function because of problems with your teeth, mouth or prostheses?					
Total score of the OHIP-14 scale*						

*The dimensional and total scores can be obtained by adding the respective item scores.

The higher the resultant score is, the lower the satisfaction of the patient is.

D1, D2, D3, D4, D5, D6 and D7: dimensions of the OHIP-14 index.

10.4a. Cuestionario OHIP-20sp (en español)

** Por favor indique su grado de acuerdo con las siguientes afirmaciones y proporcione la puntuación adecuada en cada caso:*

Perfil de Impacto de Salud Oral (OHIP-20sp)		**Nunca (0)**	**Rara vez (1)**	**Ocasionalmente (2)**	**Algunas veces (3)**	**Muchas veces (4)**
				Puntuación por ítem y por dimensión*		
D1.	***LIMITACIÓN FUNCIONAL***					
1.	¿Ha tenido dificultades mordiendo algún alimento por problemas con sus prótesis?					
2.	¿Ha notado retención de alimentos entre sus prótesis?					
3.	¿Ha sentido que sus prótesis no ajustan adecuadamente?					
D2.	***DOLOR FÍSICO***					
4.	¿Ha sufrido molestias dolorosas en su boca?					
5.	¿Se ha encontrado incómodo al comer algún alimento por problemas con sus prótesis?					
6.	¿Ha tenido úlceras o llagas en su boca por problemas con sus prótesis?					
7.	¿Ha notado que sus prótesis son incómodas?					
D3.	***MALESTAR PSICOLÓGICO***					
8.	¿Ha estado preocupado debido a problemas con sus prótesis?					
9.	¿Se ha sentido nervioso debido a problemas con sus prótesis?					
D4.	***DIFICULTAD FÍSICA***					
10.	¿Ha tenido que evitar comer algunos alimentos por problemas con sus prótesis?					
11.	¿Ha seguido una dieta insatisfactoria por problemas con sus prótesis?					
12.	¿Ha sido incapaz de comer con sus prótesis por problemas con ellas?					
13.	¿Ha tenido que interrumpir sus comidas por problemas con sus prótesis?					
D5.	***DIFICULTAD PSICOLÓGICA***					
14.	¿Se ha sentido disgustado por problemas con sus prótesis?					
15.	¿Se ha sentido avergonzado frente a otras personas por problemas con sus prótesis?					
D6.	***DIFICULTAD SOCIAL***					
16.	¿Ha evitado relacionares con la gente por problemas con sus prótesis?					
17.	¿Ha sido menos tolerante con su pareja o familia por problemas con sus prótesis?					
18.	¿Ha estado irritable con otras personas por problemas con sus prótesis?					
D7.	***EN DESVENTAJA/HÁNDICAP***					
19.	¿Ha sido incapaz de disfrutar de la compañía de otra gente por problemas con sus prótesis?					
20.	¿Ha sentido que la vida en general es menos satisfactoria por problemas con sus prótesis?					
Puntuación total del OHIP-20*						

* La puntuación total y la puntuación de cada dimensión será la suma de los marcajes de los respectivos ítems.

Cuanto mayor sea la puntuación total, menor será la satisfacción del paciente.

D1, D2, D3, D4, D5, D6 y D7: dimensiones del índice OHIP-20sp.

10.4b. Cuestionario OHIP-20 (en inglés)

** Please indicate your level of agreement with the following statements and give the appropriate score in each case:*

Oral Health Impact Profile (OHIP-20)		Never (0)	Hardly ever (1)	Occasionally (2)	Fairly often (3)	Very often (4)
				*Item and dimensional scores**		
D1.	***FUNCTIONAL LIMITATION***					
1.	Have you had difficulty chewing any foods because of problems with your prostheses?					
2.	Have you had trapped food in your prostheses?					
3.	Have you felt that your prostheses do not fit properly?					
D2.	***PHYSICAL PAIN***					
4.	Have you had painful aching in your mouth?					
5.	Have you found it uncomfortable to eat any foods because of problems with your prostheses?					
6.	Have you had sore spots in your mouth?					
7.	Have you felt uncomfortable with your prostheses?					
D3.	***PSYCHOLOGICAL DISCOMFORT***					
8.	Have you been worried because of your prostheses?					
9.	Have you been self conscious because of problems with your prostheses?					
D4.	***PHYSICAL DISABILITY***					
10.	Have you had to avoid eating some foods because of problems with your prostheses?					
11.	Has your diet been unsatisfactory because of problems with your prostheses?					
12.	Have you been unable to eat with your prostheses because of problems with them?					
13.	Have you had to interrupt meals because of problems with your prostheses?					
D5.	***PSYCHOLOGICAL DISABILITY***					
14.	Have you been upset because of problems with your prostheses?					
15.	Have you felt embarrassed because of problems with your prostheses?					
D6.	***SOCIAL DISABILITY***					
16.	Have you avoided going out because of problems with your prostheses?					
17.	Have you been less tolerant with your spouse or family because of problems with your prostheses?					
18.	Have you been irritable with other people because of problems with your prostheses?					
D7.	***HANDICAP***					
19.	Have you been unable to enjoy other people´s company because of problems with your prostheses?					
20.	Have you felt that life, in general, is less satisfying because of problems with your prostheses?					
Total score of the OHIP-20 scale*						

*The dimensional and total scores can be obtained by adding the respective item scores.

The higher the resultant score is, the lower the satisfaction of the patient is.

D1, D2, D3, D4, D5, D6 and D7: dimensions of the OHIP-20 index.

10.5a. Cuestionario QoLIP-10 (en español)

** Por favor indique su grado de acuerdo con las siguientes afirmaciones y proporcione la puntuación adecuada en cada caso:*

Calidad de vida con implantoprótesis (QoLIP-10)		**Totalmente en desacuerdo (- 2)**	**En desacuerdo (- 1)**	**Indeciso, indiferente, neutro (0)**	**De acuerdo (+ 1)**	**Totalmente de acuerdo (+ 2)**
				Puntuación por ítem y por dimensión*		
D1.	***BIOPSICOSOCIAL***					
1.	Vd. nunca ha sentido molestias dolorosas relacionadas con su implantoprótesis					
2.	Vd. mastica satisfactoriamente con su implantoprótesis					
3.	Vd. nunca ha estado preocupado o estresado debido a problemas con su implantoprótesis					
4.	Vd. nunca ha estado malhumorado con los demás por problemas con su implantoprótesis					
5.	Vd. nunca ha tenido dificultad para realizar sus actividades diarias por problemas con su implantoprótesis					
D2.	***ESTÉTICA DENTO-FACIAL***					
6.	Vd. está satisfecho con la apariencia estética de su implantoprótesis					
7.	Vd. está satisfecho con la naturalidad (realismo) de su implantoprótesis					
8.	Vd. está satisfecho con su sonrisa					
D3.	***RENDIMIENTO FUNCIONAL***					
9.	Vd. nunca ha tenido dificultades o limitaciones para hablar debido al uso de su implantoprótesis					
10.	Vd. nunca ha tenido dificultad para realizar su higiene oral debido a su implantoprótesis					
Puntuación total del QoLIP-10*						

* La puntuación total y la puntuación de cada dimensión será la suma de los marcajes de los respectivos ítems (los signos negativos y positivos deben considerarse).

Cuanto mayor sea la puntuación total, mayor será la satisfacción del paciente (es decir, que los resultados negativos o bajos positivos indican pobre auto-percepción de QoL).

D1, D2, y D3: dimensiones del índice QoLIP-10.

10.5b. Cuestionario QoLIP-10 (en inglés)

** Please indicate your level of agreement with the following statements and give the appropriate score in each case:*

Quality of Life with Implant-Prostheses (QoLIP-10)		**Strongly disagree (- 2)**	**Disagree (- 1)**	**Indecisive, indifferent or neutral (0)**	**Agree (+ 1)**	**Strongly agree (+ 2)**
				Item and dimensional scores*		
D1.	***BIOPSYCHOSOCIAL***					
1.	You have never had oral pain related to wearing implant prostheses					
2.	You have a satisfactory chewing function with your implant prostheses					
3.	You have never been worried/concerned because of problems with your implant prostheses					
4.	You have never been angry with others because of problems with your implant prostheses					
5.	You have never had difficulties in doing daily living activities because of problems with your implant prostheses					
D2.	***DENTAL-FACIAL AESTHETICS***					
6.	You are satisfied with the appearance of your implant prostheses					
7.	You are satisfied with the realism of your implant prostheses					
8.	You are satisfied with your smile					
D3.	***PERFORMANCE***					
9.	You have never had speech difficulties or restrictions related to wearing implant prostheses					
10.	You have never had oral hygiene difficulties due to the implant prostheses					
Total score of the QoLIP-10 scale*						

* The dimensional and total scores can be obtained by adding the respective item scores (the negative and positive signs must be considered).

The higher the resultant score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer self-perceived QoL).

D1, D2, and D3: dimensions of the QoLIP-10 index.

10.6a. Cuestionario QoLDAS-9 (en español)

** Por favor indique su grado de acuerdo con las siguientes afirmaciones y proporcione la puntuación adecuada en cada caso:*

Calidad de vida asociada a la satisfacción dental estética (QoLDAS-9)		**Totalmente en desacuerdo (- 2)**	**En desacuerdo (- 1)**	**Indeciso, indiferente, neutro (0)**	**De acuerdo (+ 1)**	**Totalmente de acuerdo (+ 2)**
				Puntuación por ítem y por dimensión*		
D1.	***ESTÉTICA PSICO-FACIAL***					
1.	Vd. nota que ha mejorado su perfil facial gracias a la rehabilitación protética					
2.	Vd. nota que tiene el labio menos hundido gracias a la rehabilitación protética					
3.	Vd. se siente más seguro de sí mismo gracias a la rehabilitación protética					
D2.	***ESTÉTICA INTERACTIVA***					
5.	Vd. no cambiaría nada de los dientes de su prótesis					
6.	Vd. se siente más joven gracias a su rehabilitación protética					
7.	Vd. siente que el tratamiento ha mejorado sus relaciones sociales					
D3.	***ESTÉTICA SOCIO-DENTAL***					
8.	Vd. está contento con el tamaño de los dientes de su prótesis					
9.	Vd. está contento con la exposición de diente cuando ríe					
10.	Vd. ha sido felicitado por su tratamiento protético dental					
Puntuación total del QoLDAS-9*						

* La puntuación total y la puntuación de cada dimensión será la suma de los marcajes de los respectivos ítems (los signos negativos y positivos deben considerarse).

Cuanto mayor sea la puntuación total, mayor será la satisfacción del paciente (es decir, que los resultados negativos o bajos positivos indican pobre auto-percepción de QoL).

D1, D2, y D3: dimensiones del índice QoLDAS-9.

10.6b. Cuestionario QoLDAS-9 (en inglés)

** Please indicate your level of agreement with the following statements and give the appropriate score in each case:*

Quality of Life associated Dental Aesthetic Satisfaction (QoLDAS–9)		**Strongly disagree (- 2)**	**Disagree (- 1)**	**Indecisive, indifferent or neutral (0)**	**Agree (+ 1)**	**Strongly agree (+ 2)**
				Item and dimensional scores*		
D1.	***PSYCHO-FACIAL AESTHETIC***					
1.	You have noticed an improvement of your facial profile because of the prosthetic rehabilitation					
2.	You have noticed an improvement of your lip support because of the prosthetic rehabilitation					
3.	You feel more confident because of the prosthetic rehabilitation					
D2.	***INTERACTIVE AESTHETIC***					
5.	You would not change the prosthetic teeth					
6.	You feel younger because of the prosthetic rehabilitation					
7.	You have noticed an improvement of your social relations because of the prosthetic rehabilitation					
D3.	***SOCIO-DENTAL AESTHETIC***					
8.	You are satisfied with the teeth size of the prosthetic rehabilitation					
9.	You are satisfied with the length of the teeth during laughing					
10.	You have received congratulations because of the prosthetic rehabilitation					
Total score of the QoLDAS-9 scale*						

*The dimensional and total scores can be obtained by adding the respective item scores (the negative and positive signs must be considered).

The higher the resultant score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer self-perceived QoL).

D1, D2, and D3: dimensions of the QoLDAS-9 index.

10.7. Resumen de la Tesis Doctoral en Inglés

Title: 'Study about the impact on the quality of life of candidates for dental prosthetic treatment by the development and application of specific indices'.

Abstract:

The modern approach to health that includes the patient's appropriate functioning and well-being comprises the use of patient-based outcomes for measuring both the effectiveness and the impact of the therapy. Therefore, there is a growing interest for understanding the concept of Oral health-related quality of life (OHRQoL) and the psychometric instruments designed to assess patient satisfaction.

Knowledge of these scales of OHRQoL will facilitate their systematic integration in clinical trials and health programs to evaluate the impact of oral rehabilitations in the OHRQoL. Thus, the main objectives of this investigation were: *1)* to understand and manage the psychometric and psychophysical bases of generic OHRQoL measuring instruments; *2)* to accomplish the validation process of a specific index for cemented implant-prosthesis wearers; and, finally, *3)* to develop a new, short, specific scale for assessing the Oral aesthetic-related quality of life (OARQoL), as an original concept to be considered in edentulous patients who wear dental restorations.

Accordingly, this PhD thesis comprises three successive articles published in *Medicina Oral, Patología Oral y Cirugía Bucal*, which is a J.C.R. journal situated in the third quartile of the specialty: 'Dentistry, Oral Surgery & Medicine' (position: 52/82 and impact factor of 1.095 in 2013, when the first article was published); and in the *Journal of Dentistry*, which is a J.C.R. journal located in the upper quartile of the same specialty (position: 13/87 and impact factor of 2.749 in 2015, when the second and third articles were published).

The first article was entitled: ***'Oral health-related quality of life in complete denture wearers depending on their socio-demographic background, prosthetic-related factors and clinical conditions'.*** The aim of the study was to investigate the differences in impact on oral health-related quality of life (OHRQoL) among complete denture wearers. Fifty-one patients answered the 'Oral Health Impact Profile (OHIP-14sp)' questionnaire. Socio-demographic, health variables and prosthesis-related data were gathered. The most affected domains were 'Functional limitation' and 'Physical pain'. The study concluded that the *Prosthesis location* significantly influenced the overall patient satisfaction, the lower dentures being the less comfortable. Having a complete removable denture as *Antagonist* significantly hampered the patient satisfaction. Patients without *Prosthetic stomatitis* and those who *Need repairing or changing* their prostheses recorded significantly higher OHIP-14sp total scores, and thus, lower satisfaction.

The second article, entitled: ***'Validation of the 'Quality of life with implant prostheses (QoLIP-10)' questionnaire for wearers of cement-retained implant-supported restorations';*** aimed to validate the 'Quality of Life with Implant-Prostheses (QoLIP-10)' questionnaire for assessing the impact of cemented implant-supported rehabilitations on Oral health-related quality of life (OHRQoL). Eighty-four subjects wearing implant restorations were distributed in four groups: screwed and cemented FDPs (fixed dental prostheses) supported by 2 or 3-5 implants. Impacts on OHRQoL were evaluated using the QoLIP-10 and the Oral Health Impact Profile (OHIP-14sp) scales. Data related to global oral satisfaction, socio-demographics, health-behaviours, and prostheses were gathered. The QoLIP-10 confirmed its psychometric capacity for cemented implant prosthesis wearers. This study concluded that patient satisfaction

depends upon the extension and the type of retention of implant FDPs. The QoLIP-10 attributed the significantly worst QoL to long-span cemented prostheses. When compared to screwed FDPs, short cemented implant restorations lead to greater improvements in patients' self-perceived QoL.

Finally, the third article, entitled: ***'Oral aesthetic-related quality of life of muco-supported prosthesis and implant-retained overdenture wearers assessed by a new, short, specific scale (QoLDAS-9)';*** aimed to validate a new questionnaire for evaluating the 'Oral aesthetic-related quality of life (OARQoL)' of prosthetically restored patients. 'OARQoL' assesses the impact of the self-perceived dental aesthetics on patients' well-being. This specific scale was named 'Quality of Life associated with Dental Aesthetic Satisfaction (QoLDAS-9)'. Seventy patients bearing muco-supported complete dentures or implant-retained overdentures answered the QoLDAS-9 and the Oral Health Impact Profile (OHIP-20sp) questionnaires. The QoLDAS-9 confirmed its psychometric capacity for assessing the OARQoL of CD and IO wearers. The QoLDAS-9 scale was reliable and valid. The factor analysis confirmed the existence of three dimensions ('Psycho-facial aesthetic', 'Interactive aesthetic', and 'Socio-dental aesthetic'). Both groups showed comparably high OARQoL.

General conclusions of the entire investigation:

Regardless of having managed generic questionnaires to investigate the OHRQoL in the study population, the specific index QoLIP-10 was validated for wearers of cemented implant restorations. Once the team had acquired the appropriate knowledge and experience, the main step of our investigation could be accomplished: a new specific scale for measuring an original OHRQoL concept, named: 'Oral aesthetic-related quality of life (OARQoL)' was developed. This instrument (QoLDAS-9) was

designed to completely evaluate (along with other indices), the three factors that describe the clinical success in prosthetic rehabilitations of edentulous patients: function, comfort and *aesthetics*. This may be decisive, because, to date, the available generic scales only discriminated self-patient satisfaction in terms of function and comfort. Therefore, this is the first indicator focusing on aesthetic dental satisfaction.

Other conclusions were inferred from the clinical examination performed in all cases, as the use of conventional complete dentures brings negative impacts in the OHRQoL of edentulous patients, mainly in case of lower prostheses that require reparation or substitution, with a removable total denture as antagonist. In addition, the QoLIP-10 index showed that patient satisfaction depends upon the type and extension of the implant fixed dental restoration. Patient well-being was also modulated by the study variable *Complaints about the mouth.* Furthermore, complete dentures and implant overdentures are predictable treatment options for improving the OARQoL, showing comparably high OARQoL. In terms of aesthetic satisfaction, superior education degrees lead to lower OARQoL when using the QoLDAS-9 index. Thus, the information given in the three articles will be helpful in achieving more suitable subject-oriented solutions taking into account the particular characteristics of prosthetic restorations, and also the socio-demographic and clinical profile of future patients.